2015-1498, - 1503

United States Court of Appeals for the Federal Circuit

HOWMEDICA OSTEONICS CORP.,

Appellant,

v.

SMITH & NEPHEW, INC., ZIMMER, INC.,

Cross-Appellants.

On Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board Appeal No. 2013-007710 Concerning the Inter Partes Reexamination of U.S. Patent No. 6,818,020 Control No. 95/000,428

CORRECTED OPENING BRIEF FOR APPELLANT HOWMEDICA OSTEONICS CORP.

PATRICIA J. MCGRATH
(Principal Counsel of Record)
TIMOTHY J. MALLOY
CHRISTOPHER M. SCHARFF
MCANDREWS, HELD & MALLOY, LTD.
500 West Madison Street
Suite 3400
Chicago, Illinois 60661
(312) 775-8000

Counsel for Appellant, Howmedica Osteonics Corp.

September 24, 2015

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

APPELLANT'S CERTIFICATE OF INTEREST

The undersigned counsel of record for the Appellant hereby certifies the following in compliance with Federal Circuit Rule 47.4:

1. The full name of every party or amicus represented by me is:

   Howmedica Osteonics Corp.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

   None.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

   Howmedica Osteonics Corp. is an indirect wholly owned subsidiary of Stryker Corporation. No publicly held corporation owns more than 10% of Stryker Corporation's stock.

4. The names of all law firms and the partners or associates that have appeared for the party or amicus now represented by me in the trial court or agency or are now expected to appear in this court are:

   McAndrews, Held & Malloy, Ltd.: Patricia J. McGrath; Gregory J. Vogler; Timothy J. Malloy; Christopher M. Scharff

Dated: September 24, 2015

/s/ Patricia J. McGrath
Patricia J. McGrath

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STATEMENT OF RELATED CASES

No other appeal in or from the same proceeding in the Patent Office was previously before this or any other appellate court. Third-party Requesters (Appellees Zimmer and Smith & Nephew) and the Patent Owner have been involved in litigation regarding United States Patent No. 6,818,020 ("the '020 patent") in the U.S. District Court for the District of New Jersey, since February 15, 2005, Case No. 2:05-cv-00897-WHW-CCC. During the litigation, an appeal from that case relating to other patents was previously before this Court in Federal Circuit Docket No. 2010-1162. The case has been stayed since September 30, 2009 pending the resolution of the *inter partes* reexamination of the '020 patent and will be affected by this Court's decision in the pending appeal.

JURISDICTIONAL STATEMENT

This an appeal from a final decision of the United States Patent and Trademark Office's ("PTO") Patent Trial and Appeal Board (the "Board"). This Court has appellate jurisdiction over this appeal under 28 U.S.C. §1295(a)(4)(A).

STATEMENT OF ISSUES

1. Whether the Board erred in determining that the preamble "medical implant" is not a claim limitation, and subsequently erred in finding anticipation by inherency based on Lue as evidenced by the Declaration of Zimmer/S&N's expert Dr. Clough (the "Clough Declaration"), where the alleged Clough reproduction of Lue used a material unsuitable as a "medical implant."

2. Whether the Board misapplied the legal requirements for *prima facie* inherent anticipation by applying a new legal standard—that one asserting invalidity need only take "reasonable steps" to attempt to reproduce a prior art composition for testing—where such legal standard contradicts the Federal Circuit's law that inherency may not be established by probabilities or possibilities.

3. Whether the Board erred in finding inherent anticipation based on Lue as evidenced by the Clough Declaration, where Lue fails to disclose its material by name, type, grade or identifying characteristics, making it virtually impossible for Clough to have accurately reproduced Lue's material or determine that Lue's material "necessarily" possesses the '020 patent's claimed properties.

4. Whether the Board erred in finding anticipation by inherency based on Lue as evidenced by the Clough Declaration, where Clough failed to test a material that is an accurate reproduction of the material disclosed in Lue, by deviating from the processing steps disclosed in Lue.

5. Whether the Board erred in finding inherent anticipation based on Lue as evidenced by the Clough Declaration, where Clough used an incorrect test method on the alleged Lue reproductions that gave false results.

STATEMENT OF THE CASE

Howmedica Osteonics Corp. ("Howmedica") initiated a lawsuit in February 2005 against Zimmer and Smith & Nephew ("Zimmer/S&N") for infringement of four patents, including the '020 patent. *See Howmedica Osteonics Corp. v. Zimmer, Inc., Centerpulse Orthopedics (f/k/a Sulzer Orthopedics) and Smith & Nephew, Inc*., Civil Action No. 05-CV-0897 (D.N.J.). On January 22, 2009, Zimmer/S&N, as Third-Party Requesters, jointly filed a Request for *Inter Partes* Reexamination of the '020 patent, and thereafter successfully moved the District Court for a stay of the litigation pending the reexamination proceedings.

This appeal challenges the final decision of the Board issued on December 12, 2014, declining to change its earlier Decision of April 30, 2014 affirming the Examiner's rejection of claims 1-6 of the '020 patent as anticipated by the Lue reference as evidenced by the Clough Declaration. (*See* A1-41.)

STATEMENT OF FACTS

I. THE '020 PATENT IN REEXAMINATION

A. Background of UHMWPE Implants

Ultra-High Molecular Weight Polyethylene ("UHMWPE") is a broad classification for a type of polymer that includes a wide range of types, grades, and molecular weights. (*See* A50, 1:26-34.). UHMWPE materials were first used in orthopedic applications, including artificial replacement hip and knee joints, in the 1960's. The implants were irradiated to sterilize them. (*See* A50, 1:41-56.) Unfortunately, these irradiated implants suffered from poor wear resistance and poor oxidation resistance. (*See* A50, 2:33-38, 4:50-55.) Oxidation and wear led to deterioration of the implants. (A335-339, ¶¶131-140; A560-562, ¶¶106-109.) Deteriorated implants in turn resulted in pain for patients, often required additional surgeries, and frequently led to complications caused by the presence of wear-created UHMWPE particles ("osteolysis"). (*Id*. (all).) These problems presented significant challenges in orthopedics prior to the '020 patent. (A560, ¶107.)

B. The Breakthrough of the '020 Patent Invention

Howmedica's '020 patent discloses and claims a breakthrough technology in the field of medical implants made of UHMWPE materials. The '020 patent invention provides "a polymeric orthopedic implant having superior oxidation resistance after irradiation." (A51, 4:8-10.)

In about 1993, the inventors of the '020 patent discovered that heating

medical grade UHMWPE after irradiation for a certain time and at a certain temperature, outside the presence of oxygen, provided an implant having superior oxidation and wear resistance. The invention decreased the level of “free radicals” (i.e. un-paired electrons that can bond with oxygen to create oxidation) and increased the level of “crosslinks” (i.e. reactions between un-paired free-radicals). (*See*, *e.g.*, A51, 3:58-4:7.) The crosslinking of free radicals in UHMWPE material increases its oxidation resistance and wear resistance. (*See id*.)

The ‘020 patent’s UHMWPE medical implants are characterized by one or more of the following claimed properties:

- “*solubility of less than 80.9% in trichlorobenzene*” (“TCB”) (A54-55 at Example and Table 3 (Method D), claims 1 and 5);

- an improved “*level of free radicals in the polyethylene*” of “*1 x 10*^{17} *[spins]/gram or less*” (A53:12-13, A55 at claims 2, 5 and 6); and

- an “*oxidation index*” which does not increase with oven aging “*in air at 80ºC*” (*inter alia*) (A53 at Example and Table 1 (Method D); A55 at claims 3, 4 and 6).

Part of the invention involved achieving these properties in “surgical grade UHMWPE.” (A53, 7:21-22.) The claims accordingly require an UHMWPE “medical implant.” (A55, 12:1-23 (claims 1-6).)

One embodiment of the invention is an UHMWPE medical implant that is post-irradiation heated at 50ºC for 144 hours. (*See* A53, 7:51-55.) Other examples

include heating at "130ºC for 20 hours with the minimum time being about four hours (requiring a temperature at the high end of the range)." (*See* A52, 5:47-50.)

1. Solubility of Less Than 80.9% in Trichlorobenzene

The first claimed property indicative of increased oxidation resistance and wear resistance is a specific solubility level in a specific solvent, trichlorobenzene ("TCB"). Claim 1 requires that the UHMWPE material have a "solubility of less than 80.9% in trichlorobenzene." Claim 5 requires that the solvent is "1,2,4-trichlorobenzene." Solubility in TCB relates to crosslinking. (A54, 9:49-63.) In general, a decrease in TCB solubility represents an increase in crosslinking, which in turn results in improved oxidation and wear resistance. (*See* A51, 3:58-4:7; A322, ¶57.). The inventors discovered that a solubility of less than 80.9% in TCB results in superior oxidation resistance and wear resistance. (*See* A54, 10:33-35.)

The '020 patent describes how to determine this TCB solubility, as follows:

> To determine the extent of crosslinking (solubility), a two hundred milligram sample cut from sheets were dissolved in 100 cc of 1,2,4-trichlorobenzene. Each sample was then heated to approximately 170°C with N-phenyl-2-naphthyla-mine antioxidant added for 6 hours. The samples were then hot filtered at approximately 170°C using separate preweighed high temperature filters for each sample.

(A54, 9:49-63.) The solubility test method of the '020 patent requires heating the wire mesh filter to 170°C when filtering the samples. (*Id*.) Using an unheated filter would lead to erroneously low solubility results. (*See infra*; A320-321, ¶¶52-55; A548-550, ¶¶52-54; A804-806, ¶¶25-30; A947, ¶¶9-11.)

2. Non-Increasing Oxidation Index

A second claimed property indicative of increased oxidation resistance and wear resistance is an oxidation index that does not increase over a given time period. Claim 3 requires that "the polyethylene has an FTIR (Fourier Tansform Infra-red Spectroscopy) oxidation index that does not increase in air at 80ºC for up to 11 days." Claim 4 requires an "oxidation index that does not increase in air at 80ºC for up to 23 days." And claim 6 requires "an oxidation index that does not increase in air at 80ºC for up to 11 days."

Like the solubility property discussed above, the '020 patent also discloses how to test for the claimed non-increasing oxidation index property. (*See* A53, 8:4-15.) Method D of the '020 patent meets these claim requirements.

3. Free Radicals of 1.0 X 10^{17} Spins/Gram or Less

A third property indicative of superior oxidation resistance and wear resistance is set forth in claims 2 and 6. These claims require that the "level of free radicals in the polyethylene is 1.0 x 10^{17} [spins]/gram or less."[1]

The '020 patent describes how irradiation produces free radicals in UHMWPE. (*See* A50, 1:57-65, 2:57-59.) The inventors recognized that trapped

[1] Due to a clerical error, the term "spins" was omitted from this limitation, but is part of the well-known unit of measurement. Zimmer/S&N do not dispute this fact. For example, Zimmer/S&N's expert Dr. Clough reports free radical levels as spins/gram as "set forth in the claims of the '020 Patent." (*See* A966, ¶34.)

air or moisture in UHMWPE will react with the free radicals generated during radiation to cause oxidation. (A51-52, 4:50-57, 6:20-25.) They discovered that when the UHMWPE has a certain low level of free radicals, the UHMWPE has superior oxidation resistance and superior wear resistance. (A50-52, 2:33-38, 3:65-4:7, 6:26-29, 6:54-67.) The inventors "found that an acceptable level of residual free radicals is 1.0 x 10^{17} [spins]/gram for UHMWPE for use for orthopedic implants." (A53, 7:11-13.)

C. Tremendous Success of the '020 Patent Invention

The commercial response to the '020 patent has been remarkable. Howmedica's patented products have enjoyed tremendous commercial success and have become the "gold standard" in the hip and knee replacement markets. (*See* A339, ¶¶142-143; A563-562, ¶¶117-118.) Howmedica's sales went from 100% standard polyethylene (a predecessor product) and 0% patented UHMWPE in 1996, to only 4% standard polyethylene and 96% patented UHMWPE in 2006:

Table 5: Howmedica U.S. Polyethylene Hip Mix (Units)

	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006
Standard	100%	94%	64%	35%	28%	20%	14%	9%	7%	6%	4%
Highly Cross-Linked	0%	6%	36%	65%	72%	80%	86%	91%	93%	94%	96%

(*See* A950-951, ¶¶6-8; A339, ¶143; A563-564, ¶118.)

II. THE LUE REFERENCE

Appellees Zimmer/S&N argued, in both the litigation and the presently appealed reexamination, that a paper published in 1979 entitled, "Effects of

Gamma Irradiation and Post Heat Treatments on the Structure and Mechanical Properties of Ultra High Molecular Weight Polyethylene (UHMW-PE)" ("Lue") invalidates the claims of the '020 patent. (A57-208.) They argued this despite the fact that no one prior to this lawsuit ever claimed that Lue had solved the problems of oxidation and wear of irradiated UHMWPE.

The Board correctly found that Lue fails to expressly disclose any of the claimed properties. (*See* A16.) Lue does not disclose any oxidation index or free radical test results. Lue does report solubility in xylene, but not in TCB. (*See* A16; A128-130; A148.) The Board found that Lue's xylene solubility could not be correlated to the TCB solubility required by the '020 patent. (*See* A21-22; A24; A27.)

Lue also fails to disclose information from which one could determine that any disclosed materials inherently possess the claimed properties. Lue was focused on investigating the changes in the structure and properties of polymers brought about by irradiation and heat treatment. (A58; A125.) Lue understood that "[s]mall chemical changes produced by moderate irradiation doses can cause large changes in physical properties of polymers." (A93.) Lue also noted that "the irradiation of polyethylene in the presence of oxygen led to a marked oxidation of the polymer." (A104.) Despite the known negative effects of irradiation on polymers, Lue recognized, however, that UHMWPE medical implants must be

sterilized with radiation, stating:

> When UHMW-PE is used as a component of orthopedic devices, the UHMW-PE has to be sterilized with gamma-ray [radiation] before being implanted in the human body. Although much work has been done on the irradiation of polyethylene, theories have not been satisfactorily developed. It is very difficult to interpret or predict the effects of irradiation on the polymer, because it may vary with the material and the irradiation conditions.

(A122-125.)

In addition, Lue knew about the problems associated with heating UHMW-PE, stating "usually degradation occurs during [heating/melting] processing. Due to such kind of difficulties in the processing, the uses of UHMW-PE have only recently been explored." (A87.)

In his thesis, therefore, Lue discloses the results of various heating and irradiation experiments he conducted on UHMWPE. (*See* A126.) Lue disclosed that he treated some of the UHMWPE materials with irradiation and heating as follows:

> Samples were irradiated at room temperature in two kinds of atmosphere: air and nitrogen. Two dose levels were employed; 2.5 and 5.0 Mrads. Irradiation rate was 1 Mrad/4.8 hr. The irradiation time for 2.5 and 5.0 Mrads were 12 and 24 hours, respectively. . . .
> Heat-treatments were carried out in a vacuum oven at 150ºC for one hour, followed by two different cooling processes . . .

(A126.)

The Board found that Lue's disclosure of the heating treatments alone was insufficient to infer that the resulting materials necessarily possessed any of the

'020 patent's claimed properties, stating that "annealing at 150º C for 1 hour taught by Lue is insufficient evidence to presume that claimed solubility and oxidation index would necessarily be as recited in any of the claims without additional evidence." (*See* A18-19.) In other words, the Board specifically found that Lue did not disclose a structurally identical material as the '020 patent, such that the claimed superior properties could be presumed.

Lue concluded that considerable <u>negative</u> changes in the structure and properties of UHMWPE occurred after irradiation. (A198.) He observed a color change from milky white to light yellow with irradiation. (A153.) Lue attributed this phenomenon to "an oxidation that occurred mainly on the surface of the irradiated samples." (*Id*.) In other words, Lue's irradiated UHMWPE materials oxidized—unlike the invention of the '020 patent.

Lue also reported other adverse effects of irradiation on the properties of UHMWPE stating: "In general, irradiation caused ... decreases in the molecular weight of the soluble part, tensile strength and wear resistance." (A58, *see also* A169.) Each of the reported adverse effects to the properties of Lue's UHMWPE can be attributed to the oxidation Lue observed in these materials. (*See* A324-326, ¶¶69-83; A552-554, ¶¶66-74, 78-79; A153.)

Additionally, Lue reported that heating at 150 ºC for 1 hour also negatively impacted UHMWPE properties stating: "Heat-treatment generally degraded the

properties of UHMW-PE." (A58.) "In general, heat-treatments caused a decrease in wear resistance." (A184.) Lue further discloses that post-irradiation heating "decreased" or "severely degraded" crystallinity, wear resistance, tensile strength and fatigue resistance. (A58, A197.) Each of the adverse effects on the properties that Lue reported in association with post-irradiation heating can be attributed to oxidation. (*See* A324-326, ¶¶69-83; A552-554, ¶¶66-74, 78-79; A153.)

III. FAILURE IN ZIMMER/S&N'S ATTEMPTED REPRODUCTION AND TESTING OF LUE'S MATERIAL

Given that Lue fails to disclose the claimed properties, Zimmer/S&N's expert, Dr. Clough, attempted to replicate Lue's material and then test for those properties. The following facts set forth how this attempt failed.

A. Lue's 1979 Material Versus Dr. Clough's 2007/2008 Material

1. The Material Lue Discloses (1979)

The <u>entirety</u> of Lue's description of the UHMWPE starting material is limited to the following sentence: "the material used in this study was 30 and 60 mil UHMW-PE sheet, obtained from Dixon Corporation, Bristol, Rhode Island" ("Dixon"). (A126.) Dixon is no longer in existence. Its records are gone. (*See* A633:20-A634:6; A650:20.)

Lue fails to provide any other identifying information for the UHMWPE, such as the UHMWPE resin name, grade or number. (*See id*.) Nor does Lue disclose characteristics sufficient to identify the UHMWPE. (*See id.*) Even

between the two samples that Lue used (a 30 mil sample and 60 mil sample), there were significant differences. Lue reported that "[t]he results obtained from the control non-irradiated 60 mil Dixon sheet did not agree with that obtained from the corresponding 30 mil Dixon sheet . . . This indicated that the structures of these two sheets were different." (A184 (emphasis added).)

No witness had personal knowledge to identify the UHMWPE resin used by Dixon during the Lue time frame, provided to Lue by Dixon (if anything was provided), or used by Lue for the Lue Thesis. (A650:12-A653:4; A314-316, ¶¶29, 32, 38-39; A543-545, ¶¶34-36, 42.) No documents exist identifying the UHMWPE resin material, if any, provided to Lue by Dixon or used by Dixon during the Lue timeframe. (A633:20-A634:6; A650:20-A651:15; A314-316, ¶¶29, 37; A543-544, ¶¶34, 37.)

There is simply no way of matching the exact material that Lue used with any material made today.

2. The Material Dr. Clough Used (2007-2008)

To try to replicate the material of Lue, Dr. Clough picked two possible UHMWPE materials that he believed Lue could have used. He then obtained present-day samples of the two possible UHMWPE to subsequently process and then test for the '020 patent claimed properties. But Dr. Clough's attempted

reproductions are nothing more than guesses as to the starting UHMWPE material that Lue used.

Specifically, Zimmer/S&N obtained two UHMWPE materials—GUR 4130 in 2007 and GUR 4030 in 2008—from a company called St. Gobain Performance Plastics ("St. Gobain"). (A605; A663; A964; A363-364.) St. Gobain is located at the former site of Dixon (the company from which Lue obtained his UHMWPE material). (A964, ¶¶24-25.) The sole basis for Zimmer/S&N selecting those two materials from St. Gobain were *ex parte* conversations that Zimmer/S&N had with a former Dixon employee (now employed by St. Gobain), Mr. Cativo.

During one such unsworn communication, and without documented support, in about 2005-2006, Mr. Cativo purportedly told Zimmer/S&N that he thought Dixon used GUR 403 (i.e. GUR 4030) back in 1979.[2] (A635-638.) Based on that discussion, Dr. Clough initially used what he thought was the then current GUR 4030 as his starting resin for his attempted reproductions of Lue. At his deposition, however, Mr. Cativo testified that each of those assumptions turned out to be wrong. Mr. Cativo testified that:

(1) Attorneys for Zimmer/S&N suggested GUR 4030 to him—not the other way around. (*See* A637:14-22 ("Q. Did Mr. Tate and Mr. Lennie ever tell you

[2] "GUR 403" and "GUR 4030" are interchangeable terms as are "GUR 413" and "GUR 4130." (*See, e.g.*, A619-620; A964 ¶22-25; A637.)

what material they were looking for as far as a GUR designation? A. Eventually the 403 came up in discussion – the 4030, I mean, came up in discussion…"); A657:10-22; *see also* A619:13-620:1.).

(2) The samples Mr. Cativo initially gave to Zimmer/S&N, from which Dr. Clough prepared his 2007 alleged Lue reproductions, were actually of a different resin (GUR 4130) rather than GUR 4030 as he thought. (*See* A637:23-A638:1 ("But then later found out that we have always used 4130, not 4030, at our facility in Bristol."); A656:7-657:16 ("It's an e-mail from myself to Rodger Tate explaining that, although I had thought we were using 4030 resin, that we were now using 4130."); A964, ¶24.) Only Dr. Clough's 2008 test samples used GUR 4030. (A964, ¶25; A363-364.)

(3) Mr. Cativo now believes that Dixon in fact did not even make GUR 4030 at the time of Lue in 1979. (*See* A654:8-21 ("Q. Now, is it your understanding that that statement, "samples of UHMW/PE sheet were purchased from Dixon Corporation and were reported by Dixon to be fabricated from Hoechst 4030 powder," is it your understanding that that statement is incorrect? A. [by Mr. Cativo] I can't say that it is. . . . I don't have any information to prove one way or the other. Q. Well, why do you believe it's false? A: Because we do not have the 4030 resin on our system."); *see also* A315, ¶¶31-33, 36; A544-545, ¶¶35-37, 42.)

(4) Mr. Cativo had no personal knowledge of whether Dixon ever used GUR 4130. (*See* A656:19-23 ("Q. Do you have personal knowledge that St. Gobain -- excuse me. That St. Gobain or Dixon had always been using 4130? A. This was the information I was given by our production control folks.").) None of the "production control folks" testified or submitted a declaration in the pending litigation or reexamination proceedings.

In other words, Zimmer/S&N have no admissible evidence that Lue used either of the two UHMWPE materials that Dr. Clough used for his test samples, GUR 4030 or GUR 4130. In fact, the evidence shows that it is much more likely that Lue used neither of these UHMWPE types. At the time of Lue, Dixon sold many other different types of UHMWPE, including blended and custom UHMWPE materials. (*See* A315, ¶34; A641-649, A660-661; A544, ¶36.) Mr. Cativo testified that prior to 1980, Dixon made two blended products comprised of UHMWPE, one was "PTFE filled UHMWPE" and the other was allegedly GUR 4130 "with other things blended in it." (A641-642)[3] Dixon also prepared special "custom" orders with any UHMWPE resin material, not necessarily an UHMWPE resin otherwise used by Dixon. (A643-444.) Mr. Cativo testified that one of

[3] Mr. Cativo's testimony regarding the use of GUR 4130 by Dixon constitutes unreliable and uncorroborated oral hearsay of St. Gobain unidentified "production folks."

Zimmer/S&N's attorneys arranged for the manufacture of a "custom" product that was used by Dr. Clough for one of his attempted reproductions. (*Id*.) Mr. Cativo also testified that Dixon prepared additional unknown UHMWPE materials. (A645-648.) Thus, it is entirely possible that Dixon could have made and provided to Lue an UHMWPE blended with other components such as PTFE, a custom UHMWPE chosen or provided by Lue (or a third-party) and made by a formula specified by Lue (or a third-party), or one of the other unknown UHMWPE used by Dixon. Again, Lue does not specify.

In addition, even if Lue had used GUR 4130 or GUR 4030 in the 1970's, there is no way of knowing if it was made the same way or had the same chemical structure as the GUR 4130 made in 2007/2008 and tested by Dr. Clough. (*See* A315-316, ¶¶36-39; A545, ¶¶40-42; A184.) At deposition, Mr. Cativo testified that he had no personal knowledge of the processing conditions used by Dixon in the 1970's (or St. Gobain today) to make UHMWPE materials, including key conditions such as the UHMWPE resin, temperatures and pressures. (*See* A639-640, A650-653, A656-659; A316, ¶39; A545, ¶42.) Mr. Cativo did not know whether any equipment changed over the thirty years (but it is hard to imagine that it did not). (*See* A639:7-A640:7, A659:21-23; A316, ¶39; A545, ¶42.).

3. Lue's Processing Versus Dr. Clough's Processing

In his Declaration, Dr. Clough described in conclusory fashion the irradiation and subsequent heating he used on his GUR 4130 and 4030 materials as being "in accordance with the disclosure in the Lue Thesis" and "as disclosed in Lue." (A964-965, ¶¶26-27.) At his deposition, however, Dr. Clough revealed substantial differences between the processing that he performed versus the processing that Lue disclosed. (*See, e.g.*, A316, ¶¶40-48; A545-546, ¶¶43-46.) These deviations include:

Lue's Disclosed Processing	**Dr. Clough's Processing**
Irradiated using a Gamma cell 200 irradiator (a small, portable unit)	Irradiated in glass heat-absorbing Schlenck tubes by Sterigenic's large commercial equipment.
Irradiated to 2.5 Mrads. Actual dose not measured.	Irradiated to 23.1-26.8 Kgy (2.31-2.68 Mrads) as measured by dosimeter.
Irradiation dose rate of 1 Mrad/4.8 hr (2 Kqy/hr.)	Irradiation dose rates ranging from 0.2 Kqy/hr to 1.32 Kqy/hr.
Irradiated for 12 hours.	Irradiated for 23-35 hours.
Irradiated at "room temperature" (~73°F).	Irradiated in Schlenk tubes at temperatures from 40-100°F dependent on weather conditions.

(*See* A126; A605-606; A370-375; A621-625; A663-664; A367; A316-318, ¶¶40-49; A545-547, ¶¶43-49.)

4. Lue's Reported Material Properties Versus Dr. Clough's Material Properties

Lue disclosed some visual observations and other properties of his UHMWPE materials that were very different from Dr. Clough's materials. For example, Lue observed tiny air bubbles in the original 30 mil sheet he obtained from Dixon. (*See* A153.) No air bubbles appeared in the GUR 4130 or 4030 materials used by Dr. Clough. (*See* A324, ¶¶70-71; A270 (citing Johnson Dep. Tr., 38:11-13 ("I don't recall seeing any air bubbles in the sheet."); A362:9-19.) Lue also observed that the material he obtained from Dixon was initially white palescent (milky) at room temperature, and that after irradiation, the materials turned light yellow due to the oxidation of the UHMWPE materials. (A153.) No such changes were observed or reported by Dr. Clough or his technicians. (*See* A324, ¶74; A692:10-16; A683:20-A684:9.)

Lue's testing also showed significant degradation of his processed UHMWPE. For example, Lue observed that "[i]n general, irradiation caused . . . <u>decreases</u> in the molecular weight of soluble part, tensile strength and <u>wear resistance</u>." (A58.) As another example, Lue determined that "[h]eat-treatment generally degraded the properties of UHMWPE." (*Id.*) Decreases in wear resistance, fatigue resistance and tensile strength reported are consistent with Lue's reported oxidation of his materials. (A325, ¶80; A553, ¶74.) Dr. Clough reported, however, the exact opposite. He reported that: (1) no detectable free radicals were

found, and (2) the oxidation indices did not increase after oven-aging and were nearly zero for the alleged reproductions, which indicates that Clough's materials did not oxidize and degrade as did Lue's. (A966, ¶¶33-34.)

In short, Dr. Clough's reported results are inconsistent with both the visual observations and the testing reported by Lue. (A153; A966, ¶¶33-34.)

B. Dr. Clough's Faulty Solubility Testing

Dr. Clough's testing also resulted in TCB solubility values that were suspiciously low—not just below 80.9% as required by the '020 patent claims, but nearly zero. According to his test results, he achieved TCB solubility in his alleged reproductions of between 0.7 % - 5.0 %. (*See* A965, ¶29.)

The flaw in Dr. Clough's testing lay in his failure to "hot filter" the samples, as required both by the '020 patent and industry practice. The '020 patent describes the hot filtered method as follows:

> To determine the extent of crosslinking (solubility). . . The samples were then <u>hot filtered at approximately 170°C using separate preweighed high temperature filters</u> for each sample.

(A54, 9:49-63 (emphasis added).)

The term "hot filtered," as used in the '020 patent, is a <u>term of art</u> that persons of ordinary skill in the art understand requires both a hot (wire mesh) filter and a hot filtrate (solvent and UHMWPE). (*See* A319-321, ¶¶51, 53-55; A548-

550, ¶¶52-54; A805, ¶¶26-27; A836, ¶¶13-14; A947, ¶¶9-11.) In other words, the "high temperature" filter itself must be at 170°C. (*See id*. (all).)

Howmedica's three experts, Drs. Li, Pruitt and Jordi, who each have decades of experience performing such UHMWPE solubility tests, each explained that a heated mesh filter is necessary to prevent inaccurate precipitation of solubilized UHMWPE upon contact with a cooler mesh filter, which results in erroneously low solubility results. (*Id*. (all).) The testimony of technicians Kaplar and Johnson, who performed Dr. Clough's solubility testing for Dr. Clough, shows that the testing was performed without a heated filter. (*See* A667, A668-671, A681-682; A693:9-11; A319-322, ¶¶51-57; A548-550, ¶¶50-56.) There is no evidence that Dr. Clough has any experience conducting or supervising the hot filtration of UHMWPE prior to the pending litigation. And technician Kaplar testified that she had not previously conducted solubility testing for UHMWPE. (A672:6-9.)

Kaplar and Johnson also testified that the appearance of Dr. Clough's UHMWPE samples did not change during or after the solubility testing, in color, consistency or otherwise. (*See* A672:10-A675:4; A697:17-A698:7, A699:19-A700:8 (Johnson); A321-322, ¶56-57; A550 ¶¶55-56.) These observations are inconsistent with a sample that was correctly tested for solubility. (*See* A321-322, ¶56-57; A550 ¶¶55-56.) In any successful solubility test, even if a sample has low solubility, the UHMWPE will at least swell (increase in volume), turn clear or very

translucent, and form a gooey gel after exposure to a good solvent (e.g., hot TCB) for an appropriate length of time at an appropriate temperature. (*See, e.g.*, A54 at Example 3; A319, A321, ¶51, 56; A548, A550, ¶¶51, 55.) The description of Dr. Clough's samples—no swelling, no gelling, not translucent—means that his testing failed to provide any, let alone an accurate, solubility result. (*See* A321-322, ¶¶56-57; A550, ¶¶55-56; A805, ¶¶27; A836, ¶¶13-14.)

IV. REEXAMINATION PROCEEDINGS

On January 22, 2009, Zimmer/S&N filed a Request for *Inter Partes* Reexamination ("Request") of the claims of the '020 patent. Zimmer/S&N presented over sixty-five grounds for rejection. (*See* A213-227.) The PTO granted the Request on April 9, 2009, adopting only six of the Zimmer/S&N's proposed rejections of various claims of the '020 patent. (*See* A213-217.) One basis of rejection was alleged anticipation by Lue as evidenced by the declaration of Dr. Clough and three non-prior art references authored by Wang et al. ("Wang I-III"). (*See* A213-214.) During subsequent prosecution the Examiner later adopted five additional rejections proposed by Zimmer/S&N. (A707-709, A715-720.)

Specifically, in a first Office Action mailed on April 9, 2009, the Examiner rejected claims 1-6 for alleged anticipation by Lue as evidenced by the Clough Declaration and the three Wang references. (A233-234.) Because Lue failed to expressly disclose the properties claimed by claims 1-6, the Examiner relied on the Clough Declaration and the three additional non-prior art references (Wang I-III)

as evidence of alleged inherent anticpation by Lue. (*Id.*) The Clough Declaration reports test results for solubility, oxidation index and free radical levels of UHMWPE materials prepared by Dr. Clough of alleged reproductions of the materials disclosed in Lue. (*See* A965-966 at ¶¶29, 33-34.) The Examiner found that Dr. Clough's test results support inherent anticipation by Lue of the '020 patent's claimed properties. (A233-234.) The Examiner also relied on the disclosures of the Wang I-III references as further evidence of the inherency of the claimed solubility, namely, that Lue's xylene solubility results allegedly correlated with the claimed TCB solubility. (*Id*.)

Howmedica responded to the first Office Action on June 9, 2009, providing evidence that included the declarations of Drs. Li and Pruitt to rebut the Examiner's inherency findings. (A256-281.) On October 5, 2010, the Examiner mailed a second Office action, reiterating the same rejections. (*See* A710-712, 734-739.) Howmedica responded to the second Office Action on December 6, 2010, providing further argument and evidence against alleged inherency. (A748-761.) In the Office action closing prosecution, mailed on December 10, 2011, the Examiner repeated the same rejection, using the same rationale. (*See* A854-855; A878-884.) Howmedica responded to that Office Action further advancing its arguments, including with additional evidence such as the declaration of Dr. Jordi, who specializes in material testing. (*See* A903-A917, A946-948.)

Howmedica subsequently appealed the rejection of claims 1-6 to the PTAB, on the basis that:

- Lue does not expressly disclose any of the properties of claims 1-6 or medical grade UHMWPE;
- Despite the Wang I-III references, Lue's disclosure of xylene solubility is not equivalent to, and could not be correlated to, tricholorbenzene solubility;
- Dr. Clough's attempted reproduction of Lue was not an accurate replicate because the UHMWPE used by Lue is unknown and Dr. Clough deviated from the processing parameters disclosed in Lue;
- Because Dr. Clough's attempted reproduction was not the same material disclosed in Lue, Dr. Clough's testing of the material could not show inherency of the claimed properties; and
- Dr. Clough failed to correctly perfom the hot filtered solubility test of the '020 patent, resulting in erroneous test results.

(*See* A14-39.)

The Board affirmed in part the Examiner in an April 30, 2014 Decision. (*Id*.) The Board disagreed "with the Examiner that the Wang references provide sufficient evidence that the solubility of UHMWPE in xylene at 140C and in trichlorobenzene at 170C are equivalent." (A21.) Nor was the Board "persuaded that the Wang references demonstrate any particular correlation between solubility in xylene and solubility in trichlorobenzene." (A22.) Accordingly, the Board found that Lue's disclosure of xylene solubility did not show inherency of the claimed TCB solubility. (*See* A27.)

The Board, however, affirmed the Examiner's finding that claims 1-6 were anticipated by Lue as evidenced by the Clough Declaration. (*See* A27-32.) The Board rejected Howmedica's argument that the preamble term "medical implant" is a limitation, and that Lue and the Clough reproductions failed to satisfy this limitation. (A28-29.) Instead, the Board found that "the term 'medical implant' only imports that a UHMWPE is suitable as a medical implant if it has the claimed properties." (A29.) The Board did not agree with Howmedica that UHMWPE is suitable for a medical implant only if it is medical grade, and that where it also has the claimed properties, it will have superior oxidation and wear resistance. (*Id.*)

Further, the Board found that although Lue is silent as to the type or grade of UHMWPE used in Lue's experiments, "Dr. Clough took reasonable steps to find similar UHMWPE to that available at the time of Lue." (*Id.*) On this basis, the Board relied on Dr. Clough's testing of the attempted reproductions to show the inherency of the claimed properties in Lue. (*See* A27-32.) The Board failed to comment on the other deviations that Clough made from Lue in preparing his alleged reproductions, or the many differences between Clough's alleged reproductions and the visual properties reported by Lue. (*Id.*) Nor did the Board adopt Howmedica's argument that none of Dr. Clough's attempted reproductions of Lue comprised medical grade UHMWPE, as required by the claims. (*Id.*)

The Board also found that Howmedica had submitted insufficient evidence that Clough's failure to correctly perform a "hot filtered" solubility test with a heated wire mesh screen led to inaccurate results. (*Id.*) The Board relied on Dr. Clough's solubility results, even though there is no evidence that he or his technicians had any experience performing the test on UHMWPE prior to the pending litigation. (*Id.*; A672:6-9.) Howmedica presented the testimony of three experts having multiple years of experience conducting hot filtered solubility testing of UHMWPE, who each testified that a heated wire mesh filter is required. (*See supra* and *infra*.) In addition, two of these experienced experts also testified that the test samples failed to, as they should have, swell or gel or change color during Dr. Clough's testing. (*See supra* and *infra*.) The Board, however, disregarded this evidence stating: "Dr. Clough has declared personal knowledge that the steps for the solubility testing specifically recited in the '020 were followed . . . we accord the reported visual appearance of the materials during the solubility testing little, if any probative value." (A8.)

On May 30, 2014, Howmedica requested rehearing before the Board. (A3.) The Board denied the request for rehearing on December 12, 2014. (A1-9.) Howmedica timely filed Notice of the present appeal to the Federal Circuit on February 12, 2015.

SUMMARY OF THE ARGUMENT

This appeal focuses on two main issues. The first is whether or not the preamble "medical implant," which is recited in each of the claims, is a limiting feature of the '020 patent claims. If it is, Zimmer/S&N's anticipation argument fails on its face, as their alleged "reproductions" of the Lue reference were prepared with material designated "not intended for use in medical or dental implants." The second issue relates to whether or not Zimmer/S&N's quarter of a century after-the-fact "reproductions" and testing of an alleged prior art material actually show that the prior art reference necessarily (not just possibly) possessed the claimed properties. If not, Zimmer/S&N's argument also fails because there is no inherent anticipation.

On the first issue, as a matter of law and on *de novo* review as a claim construction issue, the preamble term "medical implant" recited in claims 1-6 of the '020 patent is an essential and limiting feature of the claimed invention. The term "medical implant" describes a fundamental characteristic of the claimed invention. The entirety of the '020 patent is directed to a "medical implant." The title, abstract, background section, each of the descriptions of the preferred embodiment and each and every claim of the '020 patent recite the term "medical implant." The Summary of the Invention is replete with references to the term "medical implant" and also recites like terms including "orthopedic implant" and "orthopedic component." The Examples of the specification recite "surgical (i.e. medical) grade UHMWPE."

The Board, however, found that the recitation of a "medical implant" in the preamble was not limiting, stating that it "only imports that a UHMWPE is suitable as a medical implant if it has the properties claimed." (A29.) This holding is erroneous as a matter of law and one to which this Court need give no deference. The Board misapplied the law on preamble limitations. To read out the preamble would ignore what the inventors of the '020 patent actually invented and intended to claim—a medical implant having specific superior properties. Claims 1-6 make no sense in the context of the '020 patent if not given the meaning of a medical implant. Moreover, because not every material having the claimed properties is necessarily suitable as a medical implant, by reading out the limitation of a medical implant, the Board improperly broadened the claims beyond the actual invention—a result that shows the importance of the preamble. The term "medical implant' is a necessary limitation that gives life, meaning, and vitality to the claims.

On the second issue, Zimmer/S&N have not shown that the 1979 Lue publication inherently anticipates claims 1-6 of the '020 patent. There is no dispute that Lue fails to expressly disclose the required and claimed solubility in trichlorobenzene (claims 1 and 5), non-increasing oxidation index (claims 3, 4 and 6), or level of free radicals equal to or less than the claimed maximum (claims 2 and 6). To raise a case of inherent anticipation, Zimmer/S&N's expert (Dr. Clough) attempted to replicate and test in 2007-2008 one of the UHMWPE

materials disclosed in Lue. But for Zimmer/S&N to show that Lue inherently anticipates the claims, they must have accurately reproduced the same material disclosed in Lue, and the testing of the reproduction must have been correctly performed with accurate results.

Zimmer/S&N have failed to present a *prima facie* case of inherency through their attempted reproductions of Lue for the following reasons:

(1) There is no evidence that Zimmer/S&N started with the same UHMWPE resin as used by Lue almost 30 years earlier. That is because it is virtually impossible to know what UHMWPE Lue used. The Lue publication only vaguely discloses using UHMWPE from a company called Dixon, without specifically identifying the type of material by name, type, grade, blend, or other sufficient characteristics. No witness in the pending litigation had personal knowledge of the UHMWPE resin used by Dixon during the Lue time frame, provided to Lue by Dixon (if it had been) or used by Lue for his publication. No documents exist identifying the specific UHMWPE resin material referenced by Lue. Zimmer/S&N originally guessed Lue used a material called GUR 4030 then later guessed it was GUR 4130. Available testimony indicated that Dixon made a number of different UHMWPE materials, including different blends and different special orders. The only former Dixon employee who testified confessed to lacking any personal knowledge as to what the specific UHMWPE material was.

Inherency cannot be shown through mere guesswork, or even probabilities or possibilities, regarding the prior art.

(2) Zimmer/S&N deviated significantly from the UHMWPE processing disclosed in Lue, including irradiation, heating and cooling parameters. Expert testimony indicates that these deviations from Lue would have led to differences in the absorbed dose of irradiation and differences in the extent of crosslinking in Lue versus Clough's materials. These differences in turn would have led to differences in TCB solubility, oxidation index and free radical levels.

(3) Lue's observations of his 1979-era material before treatment and his observations of and test results for the material after irradiation and/or heat treatment are completely inconsistent with Zimmer/S&N's observations and testing of 2007-08-era material. Lue observed tiny bubbles in his starting material. Clough observed no bubbles. Lue observed yellowing of his material after processing and concluded that the change in color resulted from oxidation during processing in 1979. Clough observed no such change in color and his testing showed there had been no oxidation of his 2007-08 materials. Lue tested his processed material and concluded that the irradiation and heating of his material resulted in serious undesirable characteristics including decreases in wear resistance, tensile strength and fatigue resistance. Each of these property changes, as well as the observed yellowing, is consistent with oxidation of Lue's material.

Clough's conclusion of no oxidation of his material (prepared three decades later) is inconsistent with the property changes reported by Lue.

(4) Zimmer/S&N declined to measure molecular weight, tensile strength, wear resistance or conduct any other of the tests disclosed in Lue to verify whether Clough's 2007-08 material was the same as Lue's 1979 material.

Based on the above, Zimmer/S&N's attempted reproductions fail to show inherent anticipation, even if this Court were to find that the preamble 'medical implant' is not a limitation.

In response to these numerous failures by Zimmer/S&N to reproduce the material of Lue, the Board simply shrugged them off and created a new test for inherency. The Board found that "Dr. Clough took <u>reasonable steps</u> to find similar UHMWPE to that available at the time of Lue" and therefore concluded that "the materials used by Dr. Clough [are] sufficiently similar to those used at the time of Lue to shift the burden to Patent Owner to show that such differences are significant." (A29 (emphasis added).)

Even assuming the Board's new inherency test were appropriate, the Board never explained how Dr. Clough's numerous guesses and assumptions regarding Lue's starting material, or his numerous observed and processing deviations from what Lue did disclose, were somehow "reasonable." On the contrary, by any objective standard, Dr. Clough's steps to reproduce Lue were wholly unreasonable.

The Board's test would also set a dangerous precedent. Under the Board's new inherency test, even when a prior art reference discloses so little detail as to make it impossible to reproduce it, it would be "reasonable" to randomly fill in those details—or worse, to use hindsight and knowledge of the patent-in-suit to select those details that will give the most advantageous result.

The Board's new inherency test is also facially contrary to well-established Federal Circuit law. Under the Federal Circuit's law, inherency cannot be shown by probabilities or possibilities—rather, the claimed properties must be shown to be necessarily and inevitably present in the prior art. In other words, it is insufficient, as a matter of law, for Zimmer/S&N to show that Clough "possibly" tested the same UHMWPE that Lue used, or that the differences between Clough's processing methods and those of Lue "possibly" still resulted in the same material.

The Board also erred in shifting the burden to Howmedica to prove that the differences between the material disclosed in Lue and that of Clough were "substantial." As a matter of law, it is Zimmer/S&N's burden to show by a preponderance of the evidence that their attempted reproductions are accurate replicates of a material disclosed in Lue, including use of the same starting material <u>and</u> that Zimmer/S&N's processing accurately duplicated that of Lue. Moreover, the Board's holding in this regard misses the point entirely. It is virtually impossible to determine the TCB solubility, oxidation index and level of

free radicals of Lue without knowing what UHMWPE material Lue used. The fact that Lue is silent as to the material he made should not somehow make it easier for Zimmer/S&N to carry their burden of proof on inherency.

Further, at least Zimmer/S&N's solubility testing (directed to claims 1 and 5) is faulty and cannot show inherency of the claimed solubility in TCB. In conducting the hot filtered solubility testing, Zimmer/S&N admittedly failed to use a hot wire mesh filter in accordance with the requirements of the '020 patent's solubility test method. The Board, with little explanation, ignored that using a hot wire mesh filter is necessary to achieve correct results, despite the declarations of three experts having many years of experience conducting "hot filtered" solubility testing of UHMWPE. Instead, the Board relied on Dr. Clough's testimony that the wire mesh filter did not need to be heated, even though there is no evidence that Dr. Clough or his technicians had any experience conducting hot filtered solubility testing of UHMWPE. In addition, the testimony of Dr. Clough and his lab technicians showed that their attempted reproductions failed to gel, swell, or change at all, as they should have, during solubility testing. Howmedica's experts testified these observations and the unheated filter show that Zimmer/S&N's solubility testing was incorrectly performed, resulting in erroneously low solubility results.

For all of the above reasons, Zimmer/S&N's alleged reproductions, and their testing for the three claimed properties, fail to show *prima facie* inherent anticipation. Thus, claims 1-6 are not invalid.

ARGUMENT

I. STANDARD OF REVIEW

Claim construction is an issue of law that is reviewed *de novo*. *See Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 115 Fed. Appx. 84, 87 (Fed. Cir. 2004). Because "determining whether a preamble constitutes a limitation is a matter of claim construction," it is "likewise reviewed *de novo*." *Id*. Accordingly, review of the first issue—whether the preamble term "medical implant" is a limitation of the claims—should be performed anew.

Meanwhile, anticipation, including whether an asserted prior art reference discloses a claim limitation, is a question of fact. *See, e.g.*, *In re Rambus*, 753 F.3d 1253, 1256 (Fed. Cir. 2014). The Board's findings of fact in that regard are reviewed for "substantial evidence." *See id*. Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Rapoport v. Dement*, 254 F.3d 1053, 1058 (Fed. Cir. 2001). Importantly, however, for findings of inherent anticipation, the requirement of "substantial evidence" <u>cannot erase or lower the ultimate requirement</u> that inherency must be shown to be "necessarily" present in a prior art reference. *See*, *e.g.*, *In re Giuffrida*, 527 Fed.

Appx. 981, 984-86 (Fed. Cir. 2013) (unpublished) (no "substantial evidence" of inherency where a prior art reference that may or may not have been portable did not "necessarily" possess the claimed portability); *In re Glatt Air Techniques, Inc.*, 630 F.3d 1026, 1028-30 (Fed. Cir. 2011) (reversing Board's decision affirming the Examiner's rejection of claims, finding that the Board's finding of inherency "is not supported by substantial evidence" because the prior art did not necessarily possess the claimed limitation); *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (reversing judgment of PTO Board that prior art inherently anticipated, because there was no substantial evidence of inherency; the "Board's analysis rests upon the very kind of probability or possibility . . . that this court has pointed out is insufficient to establish inherency).

With these standards in mind, for the reasons discussed below, Howmedica respectfully submits that the Board's determination that claims 1-6 of the '020 patent are anticipated should be reversed.

II. THE BOARD ERRED AS A MATTER OF LAW BY FINDING THAT THE PREAMBLE TERM "MEDICAL IMPLANT" IS NOT A CLAIM LIMITATION

A. "Medical Implant" Is a Limitation of Claims 1-6

A claim preamble is limiting "if it recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002). The

preamble limits the claim scope where it is "essential to understand limitations or terms in the claim body." *Id*. Moreover, preambles are deemed limiting where the recited language is essential to the utility and completeness of the claimed invention. *See Boehiringer Ingelheim v. Schering-Plough*, 320 F.3d 1339, 1345 (Fed. Cir. 2003) ("[P]reamble language will limit the claim if it recites not merely a context in which the invention may be used, but the essence of the invention without which performance of the recited steps is nothing but an academic exercise."); *Griffin v. Bertina*, 285 F.3d 1029, 1034 (Fed. Cir. 2002) (preamble found limiting because the claim steps "have little meaning or utility unless they are placed within the context of the diagnosis of an increased risk of developing thrombosis, recited in the preamble.")

In *Poly-America*, the Federal Circuit addressed facts very similar to this case, and found the preamble "blown-film" to be a limitation, stating:

> We agree with Poly-America that the phrase "blown-film" is a limitation of the claims of the '047 patent. The specification is replete with references to the invention as a "blown-film" liner, including the title of the patent itself and the "Summary of Invention." The phrase is used repeatedly to describe the preferred embodiments, and the entire preamble "blown-film textured liner" is restated in each of the patents' seven claims. Our analysis shows that the inventor considered that the "blown-film" preamble language represented an important characteristic of the claimed invention.

Poly-America, L.P. v. GSE Lining Tech., Inc., 383 F.3d 1303, 1310 (Fed. Cir. 2004)

Here, the ‘020 patent’s preamble recites “a medical implant comprising . . .” That recitation of a “medical implant” is much more than merely a statement of intended use. Instead, the term “medical implant” describes a fundamental characteristic of the claimed invention that informs a person of ordinary skill in the art as to a structural requirement—that the “UHMWPE” recited in the body of the claims must be of a medical/surgical grade suitable for use in a medical implant. As such, “medical implant” explains the scope of the claims. *See Deere & Co. v. Bush Hog*, LLC, 703 F.3d 1349, 1357-59 (Fed. Cir. 2012) (the preamble term “rotary cutter deck” is a claim limitation describing “a ‘fundamental characteristic of the claimed invention’ that informs one of skill in the art as to the structure” of the claims and is necessary to understand the subject matter covered by the claims); *Vizio, Inc. v. Int’l Trade Com’n*, 605 F.3d 1330, 1340-41 (Fed. Cir. 2010) (the preamble term “for decoding” is a claim limitation and not a “statement of purpose or intended use for the invention, because ‘decoding’ is the essence or a fundamental characteristic of the claimed invention,” where the claims would have little meaning without the intended objective of decoding); *Rowe v. Dror*, 112 F.3d 473, 478-80 (Fed. Cir. 1997) (the preamble term “angioplasty” in the phrase “balloon angioplasty catheter” imposed structural limitations on the claimed catheter rather than merely specifying its intended use; an angioplasty catheter must be capable of being “inflated radially outward”).

Particularly on point is *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, where the Federal Circuit found the preamble "[a]n optical waveguide comprising" was limiting. *Corning*, 868 F.2d 1251, 1256-1257 (Fed. Cir. 1989). The Federal Circuit found that "[t]o read the claim in light of the specification indiscriminately to cover <u>all types</u> of optical fibers would be divorced from reality. The invention is restricted <u>to those fibers that work as waveguides</u> as defined in the specification. . . ." *Id*. at 1257 (emphasis added). Here, the '020 patent specification makes clear that the inventors intended to improve the properties of medical grade UHMWPE specific to medical implants, not merely make improvements to UHMWPE in general or for other uses. Indeed, the whole purpose of inventing an UHMWPE material having the claimed properties was to reduce wear and oxidation <u>in medical implants</u>, thereby reducing patient complications. (*See* A50, 2:33-38; A335-341, ¶¶131-144; A560-562, ¶¶106-109.) To read claims 1-6 to cover all types/grades of UHMWPE, and particularly, industrial grade labeled not for use in medical implants, would be divorced from the whole point of the invention.

Indeed, the '020 patent itself repeatedly underscores the critical nature of "medical implant" as a limitation of the claimed invention:

- The title is "Non-Oxidizing Polymeric Medical Implant" (A47);
- The Abstract recites the terms "medical implant" and "implant." (*Id*.);
- The Background of the Invention begins "This invention relates to medical implants . . . . " (A50, 1:20.);

- Each of the objects of the invention disclosed in the Summary of Invention relates to a medical implant. The Summary recites the like terms “orthopedic implant,” “orthopedic component,” “orthopedic applications,” “tibial tray” (i.e. knee implant) and “acetabular cup” (i.e. hip implant). (A51, 3:57-4:37.);

- The Description of the Preferred Embodiment relates entirely to medical implants. (A51-55, 4:41-11:56.)

- The Examples use “surgical [i.e. medical] grade UHMWPE.” (A53-54, 7:20-10:57.); and

- Every claim recites a “medical implant.” (A55, 12:1-54.).

The Board misapplied the Federal Circuit law and ignored the teachings of the ‘020 patent, and instead found that the recitation of a “medical implant” in the ‘020 patent’s preamble “only imports that a UHMWPE is suitable as a medical implant <u>if it has the properties claimed</u>.” (A29 (emphasis added).) This is factually incorrect (the Board cited to no evidence to support this bald assumption), and has the claim requirements backwards. Simply put, claims 1-6 require that the UHMWPE be suitable for a medical implant, first by requiring it to be medical grade. Second and separately, the claims require that the UHMWPE also have the claimed properties to achieve an improved medical implant with reduced wear and oxidation. Nothing in the ‘020 patent provides that even if <u>all</u> UHMWPE materials had the claimed properties they would all necessarily be suitable for use as a medical implant, suggesting that the preamble term “medical implant” adds nothing. To the contrary, assuming, *arguendo*, that other types or grades of UHWMPE with other inferior properties or impurities could be processed to have

the claimed properties, they would still not be capable of being used for a medical implant. (A314, ¶29.) This is especially true for UHMWPE designated not for use in medical implants. Howmedica's expert in the pending litigation, Dr. Li, whom the Board deemed a person of ordinary skill in the art at the time of the invention, explained that "[o]nly medical (i.e. surgical) grade UHMWPE is acceptable for a 'medical implant'." (*Id*. (emphasis added).)

The Board responded by pointing out that the '020 patent does allow for polymeric materials other than UHMWPE, citing the '020 patent's statement that:

> The present invention relates to a method for providing a polymeric material, such as UHMWPE, with superior oxidation resistance upon radiation. For the purpose of illustration, UHMWPE will be used as an example to describe the invention. However, all the theories and processes described hereafter should also apply to other polymeric materials such as polypropylene, high density polyethylene, polyester, nylon, polyurethane and (poly)methylmethacrylate unless otherwise stated.

(A6 (citing A51, 3:35-43.) The Board relied on this statement as alleged proof that the '020 patent contemplates the use of non-surgical or industrial-grade UHWMPE. (*Id*.) But again the Board had the '020 patent's disclosure backwards. The '020 patent simply states that other types of polymers can be used. It never says that they need not be medical grade. To the contrary, a person of ordinary skill in the art would have known at the time of the invention that any polymer used for the invention must be medical grade. (A314, ¶29.) Moreover, the only polymer required by claims 1-6 is UHMWPE.

B. Zimmer/S&N's Alleged Reproductions of Lue Did Not Use Medical Grade UHMWPE

Zimmer/S&N did not test a "medical implant" or medical-grade UHMWPE for the claimed properties. It is undisputed that for his replications, Dr. Clough used industrial grade UHMWPE GUR 4030 and GUR 4130, which are not medical (i.e. surgical) grade UHMWPE. (*See id*.; A613-614.)

Industrial grade UHMWPE, however, including the GUR 4030 and 4130 used by Dr. Clough to prepare his alleged prior art reproductions, is not acceptable for a medical implant. (*See* i*d*.) In this regard, Dr. Li testified as follows:

> GUR 4030 and GUR 4130 are both industrial grade UHMWPE implants. The Material Safety Data Sheet for GUR 4130 states that "[t]he product mentioned herein are not intended for use in medical or dental implants." ([A613], GUR 4130 MSDS.) Additionally, the packaging for GUR 4030 states that it is not suitable for medical or dental implants. ([A614], photo of GUR 4030 materials allegedly used by Requesters.)[3] Only medical (i.e. surgical) grade UHMWPE is acceptable for a "medical implant" in the United States.

(*Id*. (emphasis added).) Thus, Clough's alleged reproductions of Lue fail to meet the claim limitation "medical implant," and cannot prove inherent anticipation as a matter of law.

The Board's dismissal of Clough's failure to test a medical grade UHMWPE was erroneous for two separate reasons. First, the Board stated that "Lue describes using UHMWPE in orthopedic devices and thus teaches a medical implant. *See* Lue, Abstract and p. 52." (A28.) But the brief statement in Lue regarding

orthopedic implants describes only the background field of UHWMPE, and not the embodiment that Zimmer/S&N allege inherently anticipates the '020 patent claims. (A93 (stating that one application of UHWMPE has been in "prosthetic body implants").) Lue did not make any medical implant, but only research samples for testing. (*See* A126.) *See Synqor, Inc. v. Artesyn Techs., Inc.*, 709 F.3d 1365, 1375 (Fed. Cir. 2013) ("Anticipation requires the presence in a single prior art disclosure of all elements of a claimed invention <u>arranged as in the claim</u>.") (emphasis added). In other words, Lue fails to disclose that the UHMWPE material which he treated and tested was a medical grade UHMWPE.

Second, the real issue is whether Clough's alleged reproductions of Lue used medical grade UHWMPE. After all, the Board relied on Clough's alleged reproductions, and not any disclosure in Lue, for alleged proof of the claimed properties. Even if Lue had disclosed that his materials used medical grade UHMWPE, <u>Dr. Clough's alleged reproduction of Lue's materials did not</u>. (*See* A613-614.) In this respect, however, the Board incorrectly found that the evidence of record was persuasive that Clough's testing is "probative of surgical grades of substantially identical industrial grade UHMWPE." (A6.) There is no record evidence whatsoever that Clough's industrial grade test samples were "substantially identical" to any surgical/medical grade UHWMPE.

The Board's entire logic on this issue is circular and faulty. If, as the Board says, Lue did disclose UHMWPE for medical implants, then Clough did not accurately reproduce Lue when he used industrial-grade UHMWPE, rendering Clough's testing irrelevant. If Clough did accurately reproduce Lue by using industrial grade UHWMPE, then neither Lue nor Clough satisfies the claim element of a "medical implant."

III. THE BOARD ERRED IN FINDING INHERENT ANTICIPATION BY LUE IN VIEW OF THE CLOUGH DECLARATION–CLOUGH DID NOT ACCURATELY REPRODUCE LUE'S MATERIAL

A. The Board Misapplied the Federal Circuit's Law on Inherency and Burden of Proof

To establish anticipation under 35 U.S.C. § 102, a single piece of prior art must expressly or inherently disclose each and every limitation of a claimed invention. *See Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1255-56 (Fed. Cir. 1989) ("Anticipation requires that every limitation of the claim in issue be disclosed, either expressly or under principles of inherency, in a single prior art reference.") Here, the Board correctly found that "Lue does not teach all the properties recited in the claims." (A16.) Therefore, the Board and Zimmer/S&N turned to the doctrine of inherent anticipation.

Inherent anticipation, however, requires that a prior art reference "necessarily" possess the claimed limitation(s). *See Transclean Corp. v. Bridgewood Servs., Inc.*, 290 F.3d 1364, 1373 (Fed. Cir. 2002) ("Inherent"

anticipation is appropriate only when the prior art necessarily includes a claim limitation that is not expressly disclosed.). Inherent anticipation may not be shown by "possibilities or probabilities." *Scaltech, Inc. v. Retec/Tetra, LLC.*, 178 F.3d 1378, 1384 (Fed. Cir. 1999); *see also Mentor H/S, Inc. v. Medical Device Alliance, Inc.*, 244 F.3d 1365, 1376 (Fed. Cir. 2001) ("[T]he mere fact that a certain thing [e.g. test result] may result from a given set of circumstances is not sufficient.") (emphasis added).

For example, the fact that a composition disclosed in a prior art reference merely might possess properties claimed in a patent is insufficient to establish inherent anticipation. *See Glaxo Inc. v. Novopharm LTD.*, 52 F.3d 1043, 1047 (Fed. Cir. 1995) (evidence was insufficient to show inherency where prior art reference could have produced claimed compound or another compound); *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1554 (Fed. Cir. 1983) ("Anticipation of inventions set forth in product claims cannot be predicated on mere conjecture respecting the characteristics of products that might result from the practice of processes disclosed in references.")

Similarly, where a prior art reference contains only a vague disclosure that could be referring to any one of several possibilities, the fact that it might be referring to a claimed feature is insufficient to establish inherency. *See Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1369 (Fed. Cir. 2003)

(where a prior art reference only disclosed a "hose," it did not inherently disclose the claimed "polymeric hose"); *In re Jones*, 10 Fed. Appx. 822, 828 (Fed. Cir. 2001) (unpublished) (finding no inherency because "[t]here is no evidence in Jones's original disclosure that would suggest that the helical channel with closed ends is necessarily present. In fact, there are actually four possibilities for each helical channel . . ."); *Finnigan Corp. v. Int'l Trade Com'n*, 180 F.3d 1354, 1366 (Fed. Cir. 1999) (no inherent anticipation of claims that required "nonresonance ejection," . . . "Figure 2 might disclose a set-up for performing either resonance or nonresonance ejection. The mere possibility that Figure 2 <u>might</u> be understood by one of ordinary skill in the art to disclose nonresonance ejection is insufficient to show that it is inherently disclosed therein.") (emphasis added). Even if there are only a few possibilities for a vague statement in a prior art reference, that does not somehow constitute a disclosure of <u>all</u> possibilities. *See id.*

Particularly on point is *In re Brink*, 419 F.2d 914, 916-918 (C.C.P.A. 1970). In *Brink*, the patent claims at issue required glass fibers having specific fiber diameters and density. A prior art reference vaguely disclosed using a fiber glass mat "commercially available as Owens-Corning TWF." The Examiner cited to evidence of the properties of some of the commercially available Owens-Corning TWF. The court, however, found that it was "<u>merely speculative</u>" that the evidence related to "<u>the same material used in the reference patent</u>." *Id.* at 917

(emphasis added). The court further stated that it did "not see how a disclosure or combination of disclosures leaving one to rely on fortune in choosing the referred to material can function as an anticipation." *Id.* at 918 (emphasis added). In other words, evidence that some, not all, of the commercially available Owens-Corning TWF materials had the claimed properties was insufficient to show inherency where it was unknown whether those were the same materials referred to in the prior art reference.

Only in narrow circumstances, where a prior art reference discloses the identical chemical composition as a patent, made in the identical way as the patent, can a rebuttable presumption arise that the prior art composition will have the same properties as the patented composition. However, that presumption can arise if and only if the compositions are indeed identical. *See, e.g.*, *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990) ("when the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not") (emphasis added). The Federal Circuit has never allowed such a presumption, or otherwise shifted the burden of proof to the applicant/patentee, based only on evidence that a prior art composition is possibly the same as the claimed composition.

Additionally, in other limited circumstances, inherency can be proven using extrinsic evidence. But such extrinsic evidence is only applicable if it "makes

clear that the missing descriptive matter is necessarily present in the thing described in the reference." *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1369 (Fed. Cir. 2003). Extrinsic evidence that only raises a possibility or probability of inherency is insufficient. *See id.*

For example, inherency can be shown by reproducing something disclosed in a prior art reference, and then testing that reproduction. But any such prior art reproduction must precisely replicate the prior art and be made using the same process as the prior art. *See Glaxo Group LTD. v. Apotex, Inc.*, 376 F.3d 1339, 1348-49 (Fed. Cir. 2004) (affirming finding of no inherency where alleged reproductions of the prior art deviated from the prior art's processing method in several respects); *Cephalon, Inc. v. Watson Labs., Inc. (In re Armodafinil Patent Litig. Inc.)*, 939 F. Supp. 2d 456, 470-471, fn. 19 (D. Del. 2013) (no inherent anticipation where, in attempting to test replicated samples of the prior art, defendant's expert deviated from the express processing steps disclosed in the prior art reference, resulting in test samples that "were not the result of an accurate reproduction" of the prior art) (emphasis added); *Pfizer Inc. v. Teva Pharms. U.S.A., Inc.*, 882 F. Supp. 2d 643, 678 (D. Del. 2012) (no inherent anticipation where "the court concludes that Dr. Atwood did not adhere to the requirements [of the prior art reference] when he attempted to reproduce the chemical process described therein"); *Biacore, AB v. Thermo Bioanalysis Corp.*, 79 F. Supp. 2d 422,

439 (D. Del. 1999) (results of experiment "are of little probative value since it cannot be ascertained with any certainty whether Dr. Scouten created the same polymer disclosed in example 5"); *Promega Corp. v. Novagen, Inc,* 6 F. Supp. 2d 1037, 1063-64 (W.D. Wis. 1997) ("defendant did not replicate the prior art reactions precisely, making it questionable whether the results were reliable indicators of what had taken place in the original experiments.").

The requirement of precise replication of the prior art is critical—otherwise the later-made and tested material is not in fact the prior art, but something different from the prior art. Howmedica has not found a single Federal Circuit, district court, or PTAB decision that has found testing of something that possibly replicated the prior art to be sufficient to show *prima facie* inherency, or to satisfy the "substantial evidence" standard on review.

In the present case, Zimmer/S&N's expert (Dr. Clough) never tested any actual Lue materials from about 1979. (*See* A965-966, ¶¶21-34.) Nor did Zimmer/S&N allege that Lue discloses the same material as the '020 patent, made in the same way as the '020 patent, such that the rebuttable presumption of *In re Spada* would apply. Instead, Zimmer/S&N attempted to replicate the material of Lue and test that replication material. To make out a *prima facie* case of inherency, therefore, Zimmer/S&N had to show that (1) Clough reproduced and tested the same material as disclosed in Lue, made in the same way, and (2) that

the material "necessarily" possesses the claimed properties. *See* case law, *supra*. Evidence showing that Zimmer only possibly used the same material as Lue or processed it in the same way, or that Lue only might have possessed the claimed properties, is not "substantial evidence" of inherency. *See* case law, *supra*.

B. Zimmer/S&N's Alleged Reproduction Is Not the Same as the Material Disclosed in Lue—There is No *Prima Facie* Inherency

1. There Is No Evidence That Clough Used The Same UHMWPE Starting Material As Lue

As a matter of law, it is Zimmer/S&N's burden to first show that the starting UHMWPE resin Clough used to allegedly reproduce Lue is the same as the UHMWPE actually used by Lue—not merely one of the possible UHMWPE resins that Lue could have used. Accordingly, even if all of Zimmer/S&N's evidence is believed, because it shows at most a mere <u>possibility</u> that Zimmer/S&N actually reproduced Lue's material, the Board's decision was not based on "substantial evidence" of inherency. *See Scaltech*, 178 F.3d at 1384 (inherent anticipation may not be shown by "possibilities or probabilities").

Again, there is no dispute that Lue does not disclose the type or name of the UHMWPE starting resin that he used in his experiments or testing. Lue only states that "the material used in this study was 30 and 60 mil UHMW-PE sheet, obtained from Dixon Corporation, Bristol, Rhode Island" ("Dixon"). (A126 (Lue).) But Dixon is no longer in existence. No witness has personal knowledge to identify the

UHMWPE resin used by Lue. (*See* A650:12-A653:4; A314-316, ¶¶29, 32, 38-39; A543-545, ¶¶34-36, 42.) No documents exist identifying the UHMWPE resin material, if any, provided to Lue by Dixon, or even identifying the UHMWPE resin used by Dixon during that timeframe. (*See* A633:20-A634:6; A650:20-A651:15; A314-316, ¶¶29, 37; A543-544, ¶¶34, 37.)

The <u>sole</u> bases for Zimmer/S&N's assertion that they used the same starting resin as Lue are ex parte unsworn communications with Joseph Cativo, a former Dixon employee, and Mr. Cativo's uncorroborated <u>hearsay testimony</u>. (*See* A635-638.) According to Zimmer/S&N, Mr. Cativo first told them that Dixon would have supplied Lue with GUR 4030. (*See* A656:7-A657:16.) Then he changed his mind and said that Dixon would have supplied Lue with GUR 4130. (*Id*.) But Mr. Cativo testified at his deposition that (1) Zimmer/S&N's attorneys were the ones to suggest that Dixon had supplied Lue with GUR 4030, (2) he now believes that Dixon never made GUR 4030, and (3) he had no personal knowledge of whether Dixon ever made GUR 4130. (*See* A315-316, ¶¶32-39; A637-638, A654, A656-657; *see also* A619:13-A620:8.) In other words, Zimmer/S&N have no evidence whatsoever that Lue (or Dixon) used either of the two UHMWPE materials that Dr. Clough used for his test samples, GUR 4030 or GUR 4130.

In fact, the evidence shows that it is much more likely that Lue used <u>neither</u> of these UHMWPE types. Mr. Cativo testified that, in the late 1970's, Dixon sold

many other different types of UHMWPE, including blended and custom UHMWPE materials. (A641-649; A660-661; A315, ¶34; A544, ¶36.) Lue even discloses that the structures of the 30 and 60 mil samples he used were substantively different from one another. (A184.) It is entirely possible that Dixon could have provided to Lue any of a number of different types of UHMWPE. Again, the Lue reference itself does not specify.

In addition, Zimmer/S&N failed to provide any evidence that, even if Lue had used GUR 4130 or GUR 4030 in the 1970's, it was made the same way or had the same chemical structure as the GUR 4130 made in 2007/2008 and tested by Dr. Clough. At deposition, Mr. Cativo testified that he had no personal knowledge of the processing conditions used by Dixon in the 1970's (or St. Gobain today) to make UHMWPE materials. (*See* A658:13-A659:20; A316, ¶39; A545, ¶42.)

Accordingly, Zimmer/S&N can only, at best, show that they possibly (albeit very unlikely) used the same starting UHMWPE resin as Lue. It is just as possible that they used a resin different from Lue's. The Board, however, ignored this failure in Zimmer/S&N's evidence, and instead inexplicably found that Zimmer/S&N "took reasonable steps to find similar UHMWPE to that available at the time of Lue." (A29.) But the Board's new test--"reasonable steps to find "substantially similar" material--is wholly inconsistent with Federal Circuit law.

Zimmer/S&N's proffered evidence is the very definition of the "possibilities or probabilities" that the Federal Circuit has repeatedly held is insufficient to show inherency. *See Dayco*, 329 F.3d at 1369 (where a prior art reference did not specify the exact type of hose it used, it did not inherently disclose the claimed "polymeric hose"); *In re Jones*, 10 Fed. Appx. at 828 (finding no inherency because "[t]here is no evidence in Jones's original disclosure that would suggest that the helical channel with closed ends is necessarily present. In fact, there are actually four possibilities for each helical channel . . ."); *Finnigan*, 180 F.3d at 1354 (no inherent anticipation of claims that required "nonresonance ejection"; ". . . Figure 2 might disclose a set-up for performing either resonance or nonresonance ejection.").

This issue is remarkably similar to that in *In re Brink*, 419 F.2d 914, 916-918 (C.C.P.A. 1970), where the court found evidence of alleged inherency to be insufficient. Again, in *Brink*, the patent claims at issue required glass fibers having specific fiber diameters and density. Very similar to the instant dispute, the prior art reference in *Brink* only vaguely disclosed using a fiber glass mat "commercially available as Owens-Corning TWF." The Examiner cited to evidence of the properties of some of the commercially available Owens-Corning TWF materials. The court, however, found that it was "<u>merely speculative</u>" that the evidence related to "<u>the same material used in the reference patent</u>." *Id.* at 917 (emphasis added). The court further stated that it did "not see how a disclosure or

combination of disclosures leaving one to rely on fortune in choosing the referred to material can function as an anticipation." *Id.* at 918 (emphasis added). For the same reasons here, Zimmer/S&N and the Board cannot "rely on fortune" in choosing the starting UHWMPE that Lue might have used.

Similarly, a different panel of the Board itself recently agreed in an *inter partes* review decision that inherency cannot be shown simply by vague disclosure in a prior art reference that possibly could be referring to a claimed feature. In *Toyota Motor Corp. v. American Vehicular Sciences, LLC*, IPR2013-00419, 2015 WL 183908 (P.T.A.B. Jan. 12, 2015), the claims at issue required a "pattern recognition algorithm" generated using a specific kind of input. A prior art reference (Lemelson) only disclosed a pattern recognition algorithm that was generated using "known inputs." The Board found that where it was equally possible that the "known inputs" used by Lemelson were the claimed inputs or one of a few other different types of inputs, the prior art reference could not inherently anticipate. *See id.* at 10. The Board did not shift the burden of proof to the patent owner—as it did in this case—to prove that Lemelson did not use the type of input claimed. *See id.* The Board's contrary decision in the present case is inexplicable.

2. Dr. Clough Deviated From Lue's Processing In Preparing The Alleged Lue Reproductions

To constitute relevant evidence of the inherent properties of Lue, Zimmer/S&N also had to process the starting material of Lue in the same manner that Lue did, to arrive at the same final treated material. Under the law, even one

wrong guess or deviation is evidence that Dr. Clough's alleged reproductions are not accurate replicates of any prior art material and cannot establish inherency. *See Glaxo Group LTD.*, 376 F.3d at 1348-49 (affirming finding of no inherency where alleged reproductions of the prior art deviated from the prior art's processing method in several respects); *Cephalon, Inc.*, 939 F. Supp. 2d at 470-471, fn. 19 (no inherent anticipation where, in attempting to test replicated samples of the prior art, defendant's expert deviated from the express processing steps disclosed in the prior art reference, resulting in test samples that "were not the result of an accurate reproduction" of the prior art); *Pfizer Inc.*, 882 F. Supp. 2d at 678 (no inherent anticipation where "the court concludes that Dr. Atwood did not adhere to the requirements of Example 6 [of the prior art reference] when he attempted to reproduce the chemical process described therein").

As discussed above, however, in attempting to reproduce Lue, Dr. Clough deviated from many important processing parameters specified in Lue. (*See* A316-318, ¶¶40-49; A547, ¶¶47-49.) Dr. Clough irradiated his samples using different equipment, in a different type of heat-absorbing glass container, at a different dose rate, for a different time and at a different temperature. (*See above* at p. 18, setting forth table of differences between Clough's processing and Lue's processing.) (*See* A126; A605-606; A370-375; A621-625; A663-664; A367; A316-318, ¶¶40-49; A545-547, ¶¶43-49.) Dr. Clough's significant deviations from Lue's processing may lead to significant differences in the extent of crosslinking in Lue's

and Clough's materials, and TCB solubility, oxidation index, and free radical levels. (*See* A317-318, ¶¶46-47; A545-547¶¶43-47.)

In other words, the differences in processing between Clough's alleged reproductions and Lue's material further show that Clough's alleged reproductions are not accurate replicates of any Lue material. The Board's decision is again not supported by "substantial evidence" that Clough accurately reproduced for testing the same material as disclosed in Lue.

3. Evidence Shows That Dr. Clough's Alleged Reproductions Had Many Differences From Lue's Material

The differences in appearance and tangential properties discussed above between Lue's material and Zimmer/S&N's test material also show that Zimmer/S&N could not have reproduced the same or substantially the same material as Lue. One does not need to know exactly what material Lue used to know that Zimmer/S&N's test material was not it. *See, e.g., Glaxo*, 376 F.3d at 1348-49 (affirming finding of no inherency where evidence showed that alleged reproductions were not identical to the asserted prior art composition).

Lue reported "air bubbles" in his starting material, whereas Dr. Clough did not. (A153; A324, ¶¶70-71.) Lue reported a color change from milky white to light yellow after irradiation, while Dr. Clough did not. (*See* A324, ¶74; A692:10-16; A683:20-A684:9.) And Lue disclosed that his heat treatment "generally degraded the properties" of his material, such as decreasing wear resistance, tensile

strength, and fatigue resistance, all of which are important properties for a medical implant. (*See* A197; A324-326, ¶¶74-82; A553-554, ¶¶69-74, 78-79.) As explained by Dr. Li and Dr. Pruitt, these described decreases in wear resistance, fatigue resistance and tensile strength reported by Lue are consistent with Lue's reported oxidation of his materials. (*See* A325, ¶80; A553-554, ¶74.) In addition, decreases in other properties reported by Lue in Tables X, XII, and XIII for post-heated materials are also consistent with oxidation of the UHMWPE. An oxidized material, however, would not have the claimed properties. (*See* A325-326, ¶¶82-83; A554-555, ¶¶79-80.)

4. Zimmer/S&N Failed To Conduct Any Testing Disclosed In Lue To Show That The Alleged Reproductions Were The Same As Lue's Disclosed Material

There is also no evidence that Zimmer/S&N ever attempted to verify that their reproductions are accurate replicates of any material disclosed in Lue. In accordance with standard laboratory practice, a person of ordinary skill in the art would have conducted some or all of the tests reported in Lue to determine whether Lue's material was accurately replicated. (*See* A318-319, ¶49; A547, ¶49.) By doing such testing, one would compare their own test results to the results reported by Lue. (*Id.*) This confirmation testing would show whether the attempted reproductions had the same properties as Lue's materials.

Specifically, Lue reported results for the following tests: xylene extraction (and determination of crosslinking fraction); molecular weight determination of soluble fractions; crystallinity and morphology tests calculated from density and DSC; tensile properties, including yield strength, tensile strength and elongation; abrasion wear resistance test; mechanical fatigue behavior; and determination of dimensional stability. (A126-A146.) Zimmer/S&N failed to conduct even one of the above-listed scientific tests disclosed in Lue on the alleged reproductions. (*See* A126-A146; A269-270; A965-966, ¶¶21-34; A318-319, ¶49; A547, ¶49.) There is no evidence of comparative testing of the alleged reproductions and Lue's materials to determine whether they are the same. More particularly, there is no evidence showing that Zimmer/S&N's attempted reproductions have one, let alone all, of the properties of Lue's materials.

IV. THE BOARD OVERLOOKED THE DEFICIENCIES OF DR. CLOUGH'S SOLUBILITY TESTING, WHICH RESULTED IN INACCURATE TEST RESULTS THAT CANNOT SHOW INHERENCY

An additional and separate failure by Zimmer/S&N to show inherent anticipation stems from their expert's flawed solubility testing. Incorrectly conducted, and therefore, inaccurate, test results are probative evidence of nothing. *See* Fed. R. Evid. 702 (expert testimony is only admissible if it "is the product of reliable principles and methods"); *Johnson & Johnson Vision Care, Inc. v. CIBA Vision Corp.*, 634 F.Supp.2d 1293, 1315 (M.D. Fla. 2008) (no inherent

anticipation; "J & J has failed to establish how Robertson meets the oxygen permeability and transmissibility limitations set forth in the asserted CIBA claims, using the same measurement methodology as the CIBA patents."); *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 98 F. Supp. 2d 362, 390 (S.D.N.Y. 2000), *aff'd* and remanded, 237 F.3d 1359 (Fed. Cir. 2001) (attempted replication testing of prior art was irrelevant and inapplicable where testing deviated from the prior art reference).

A fatal flaw in Dr. Clough's testing was his failure to use "hot filtration," as required both by the '020 patent and industry practice. The '020 patent describes the hot filtered method as follows:

> To determine the extent of crosslinking (solubility). . . The samples were then <u>hot filtered at approximately 170°C using separate preweighed high temperature filters</u> for each sample.

(A54 at 9:49-63 (emphasis added).)

The term "hot filtered" itself, as used in the '020 patent, is a <u>term of art</u> that persons of ordinary skill in the art, such as Howmedica's expert witnesses Dr. Li, Dr. Pruitt and Dr. Jordi, understand require a hot heated filter. (*See* A319-321, ¶¶51, 53-55; A548-550, ¶¶52-54; A805, ¶¶26-27; A947, ¶¶9-11.) The "high temperature" wire mesh <u>filter</u> must be at 170°C. (*Id*. (all).) The Board, however, relied upon an incorrect interpretation of "hot filtered" provided by Dr. Clough, who stated that the wire mesh filter merely needs to withstand temperatures up to

170°C. That is not what "hot filtration means. (*Id*. (all).) Indeed, there is no evidence that Dr. Clough or his technicians had any experience conducting "hot filtration" solubility testing of UHMWPE prior to the pending litigation. (A672:6-9.)

The Board ignored the necessity of using a hot wire mesh filter for the '020 patent's required "hot filtered" solubility testing, despite the many years of experience that Howmedica's witnesses (Dr. Li, Dr. Pruitt and Dr. Jordi) have in conducting such "hot filtered" solubility testing of UHMWPE. (*See* A319-321, ¶¶51, 53-55; A548-550, ¶¶52-54; A805, ¶¶26-27; A836-837, ¶¶13-14; A947, ¶¶9-11.) Drs. Li, Pruitt and Jordi unequivocally testified that a heated filter is necessary to prevent precipitation of solubilized UHMWPE upon contact with an unheated filter, which may result in erroneously low solubility results. (*Id*. (all).)

The Board also ignored that UHMWPE will at least swell, turn clear or very translucent, and form a gooey gel after exposure to TCB for an appropriate length of time at an appropriate temperature. (*See* A320, ¶52; A548, ¶51.) Ms. Kaplar and Mr. Johnson testified that Zimmer/S&N's test samples did not swell, did not turn gooey or gel, or change color at all.[4] (*See* A672:10-A674:22, A675:4-18, A676:12-23, A677:3-A678:6, A679:1-12, A680:6-12; A697:17-A698:7, A699:19-

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[4] Ms. Kaplar testified that two samples gelled, which she "discarded" at Dr. Clough's direction. (A675-677.)

A700:8.) Dr. Li testified that this description of the samples during testing –no swelling, no gelling, not translucent--means that Clough's testing failed to solubilize correctly, if at all. (*See* A321-322, ¶¶56-57; A550, ¶¶55-56.)

The explanation for Dr. Clough's suspiciously low solubility results is simple. All of the solubility test results reported by Dr. Clough are about zero because the solubility test was performed incorrectly such that the material failed to properly solubilize at all (dissolve in the solvent). (*Id*.) It is simply not credible that, where the '020 patent discloses that a solubility of less than 80.9% is superior, that Dr. Clough's samples were somehow so superior that they resulted in near 0%. Dr. Clough's samples did not change (solubilize or gel) at all during testing, as the technicians testified,[5] because they were not exposed to the correct conditions. The material collected on the wire mesh filter does not reflect the real gel content of the material tested, but instead simply the original test sample unchanged. (*See* A321-322, ¶¶56-57.) The sample weights recorded before and after testing are nearly identical because nothing was effectively done to the samples. As an extreme example to illustrate the point, if one were to try to test the solubility of salt in water, but yet used a frozen block of ice for the water, one would not get the correct result for the solubility of salt in water.

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[5] In all likelihood, the two samples "discarded" by Ms. Kaplar are the only of Dr. Clough's samples to have properly gelled during solubility testing. (A675-676.)

Accordingly, for the reasons discussed, Dr. Clough's flawed solubility testing is not evidence of the inherent properties of the Lue material, as his testing gave erroneously low results.

CONCLUSION AND STATEMENT OF RELIEF SOUGHT

For the foregoing reasons, Howmedica respectfully requests that the Court reverse the decision of the Board finding claims 1-6 of the '020 patent anticipated by the Lue reference as evidenced by the Clough Declaration.

Respectfully submitted,

Dated: September 24, 2015

/s/ Timothy J. Malloy
Timothy J. Malloy
Patricia McGrath
Christopher Scharff
McANDREWS, HELD & MALLOY, LTD.
500 West Madison Street, 34th Floor
Chicago, Illinois 60661
Phone: 312-775-8000
Fax: 312-775-8100

ADDENDUM

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LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK
600 SOUTH AVENUE WEST
WESTFIELD, NJ 07090

EXAMINER	
Jastrzab, Krisanne	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW, INC. AND ZIMMER, INC.
Requester

v.

HOWMEDICA OSTEONICS CORP.
Patent Owner and Appellant

Appeal 2013-007710
Reexamination Control 95/000,428
Patent 6,818,020 B2
Technology Center 3900

Before MARK NAGUMO, RICHARD M. LEBOVITZ, and
RAE LYNN P. GUEST, *Administrative Patent Judges*.

GUEST, *Administrative Patent Judge*.

DECISION ON REHEARING

In the Decision on Appeal dated April 30, 2014 ("Decision"), the panel affirmed the Examiner's rejection of claims 1-6 of U.S. Patent 6,818,020 B2 (hereinafter, "the '020 Patent") under 35 U.S.C. § 102(b) as anticipated by Lue,[1] as evidenced by the Clough Declaration.[2]

Patent Owner requests rehearing of this decision under 37 C.F.R. § 41.79. Request for Rehearing ("Req. R'hg.") dated May 30, 2014. Requester submitted comments on Patent Owner's Request for Rehearing on June 30, 2014 (hereinafter "Comments").

Initially, Patent Owner contends the Board misapprehended or overlooked that:

I. The preamble phrase "medical implant" limits the claims to a grade of Ultra high molecular weight polyethylene (hereinafter "UHMWPE") suitable for a medical implant. Req. R'hg. 5.

II. Dr. Clough's use of industrial grade UHMWPE cannot be used to show anticipation by inherency because Requester has not provided sufficient evidence that the industrial grade

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[1] Ching-Tai Lue, "Effects of Gamma Irradiation and Post Heat-Treatments on the Structure and Mechanical Properties of Ultra High Molecular Weight Polyethylene (UHMW-PE)," Masters Thesis, University of Lowell, 1979 (hereinafter referred to as "Lue").

[2] First Declaration of Roger L. Clough, dated January 16, 2009, and made of record as Appendix B to the Request on January 22, 2009 (hereinafter "Clough Declaration" or "Clough Decl."). The Clough Declaration is further supported by additional testimony of Dr. Clough in the Second Clough Declaration, dated July 9, 2009, and made of record on the same date with Requester's Comments (hereinafter "2nd Clough Declaration" or "2nd Clough Decl."), and in the Third Clough Declaration, dated January 1, 2011, and made of record on January 5, 2011 with Requester's Comments (hereinafter "3rd Clough Declaration" or "3rd Clough Decl.").

UHMWPE tested by Dr. Clough is either medical grade or the same UHMWPE used by Lue. Req. R'hg. 8-12.

III. The evidence and explanations that definitively show that Dr. Clough's testing was faulty. Req. R'hg. 12-15.

I. Interpretation of preamble phrase "medical implant"

Claim 1, as a representative claim, reads as follows:

> 1. A medical implant comprising an irradiated ultra-high molecular weight polyethylene having a weight average molecular weight greater than 400,000 and a solubility of less than 80.9% in trichlorobenzene.

Patent Owner contends that the preamble phrase "medical implant" is not a statement of purpose or intended use. Req. R'hg. 4-5. Rather, Patent Owner argues that the phrase provides a structural limitation requiring a grade of UHMWPE suitable for use as a medical implant. *Id.* at 5.

After carefully consideration of Patent Owner's contentions, we are not persuaded that the panel misapprehended or overlooked the concerns raised by Patent Owner in interpreting the preamble phrase "medical implant." The Decision follows *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997), which states that "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation." The claims of the '020 patent define in their body "an irradiated ultra-high molecular weight polyethylene" having particular properties. Thus, the body of the claims recite a structurally complete invention. The body of the claims are silent as to any particular grade of UHMWPE. Further, Patent Owner did not persuasively identify disclosure in the '020 Patent that would

have led one of ordinary skill in the art to construe "medical implant" narrowly to require a specific grade of UHMWPE. Consistently, the panel determined in the Decision that "We disagree that the recitation in the preamble of a 'medical implant' structurally defines the UHMWPE otherwise recited in the claims." Decision 18.

Accordingly, the panel did not misapprehend or overlook the phrase "medical implant" in the preamble of claim 1.

Further, even if the phrase "medical implant" required that the prior art teach UHMWPE suitable for use as a medical implant, Lue states that UHMWPE was extensively used "for prosthetic body implants," particularly for "use in artificial hips, fingers, knees, etc." as "the best material available for these applications." Lue, p. 23, third full ¶. Thus, Lue expressly teaches treated UHMWPE that is suitable for use as medical implant.

II. Dr. Clough's use of industrial grade UHMWPE

Patent Owner contends that Dr. Clough's use of industrial grade UHMWPE cannot be used as evidence to show anticipation by inherency because "[w]ithout a showing that Lue used GUR 4030 or 4130 [the industrial grade UHMWPE used by Dr. Clough] or a showing that one or both are in fact the same or sufficiently similar to the UHMWPE used by Lue, a finding of inherency is precluded." Req. R'hg. 11.

The panel did not overlook either the difference in grade of Dr. Clough's UHMWPE samples or the silence in Lue as to the grade used. The Decision states

> Lue was silent as to the type or grade of UHMWPE treated according to the process that he discloses. We find that Dr. Clough took reasonable steps to find similar UHMWPE to that

> available at the time of Lue. Clough Decl. ¶¶ 23-26. Accordingly, we find that the materials used by Dr. Clough to be sufficiently similar to those used at the time of Lue to shift the burden to Patent Owner to show that such differences are significant. Patent Owner has directed us to no persuasive evidence to show that particular resins or grade used by Dr. Clough would have created a significant difference in Dr. Clough's results.

Decision 19. In other words, the evidence of record is persuasive that GUR 4030 or 4130 are "sufficiently similar to the UHMWPE used by Lue" for a finding of inherency. Accordingly, it has not been shown that it would have been necessary for Dr. Clough to reproduce all the testing described in Lue to show the identical nature of the UHMWPE tested by Lue. On the present record, Dr. Clough's testing is probative of surgical grades of substantially identical industrial grade UHMWPE.

Moreover, the '020 patent suggests that differences in the types or grades of UHMWPE are unlikely to substantially change the effects of an identical process. For example, while the '020 patent uses "surgical grade UHMWPE" in its examples (*see* '020 patent, col. 7, ll. 21-22), the '020 patent is otherwise silent as to any particular grade. Further, the '020 patent states that

> The present invention relates to a method for providing a polymeric material, such as UHMWPE, with superior oxidation resistance upon irradiation. For the purpose of illustration, UHMWPE will be used as an example to describe the invention. However, *all the theories and processes described hereafter should also apply to other polymeric materials such as polypropylene, high density polyethylene, polyester, nylon, polyurethane and poly(methylmethacrylate) unless otherwise stated.*

'020 patent, col. 3, ll. 35-43 (emphasis added).

Accordingly, the panel did not misapprehend or overlook Dr. Clough's use of industrial grade UHMWPE.

III. Evidence that Dr. Clough's testing was faulty

Patent Owner directs us to Ms. Mary Kaplar's[3] testimony, presented as an Exhibit A to Dr. Li's declaration, that there were 15 minutes between samples as contradicting Dr. Clough's testimony that the samples were not cooled, but still at 170°C. Req. R'hg. 12.

Ms. Kaplar's testimony is not contradictory, as argued by Patent Owner. As stated in the Decision, Dr. Clough testified that the samples were kept in insulating heating mantles, were not left at room temperature, were still at 170°C, and were not cooled. Decision 21 (citing Third Clough Declaration ¶ 8 and ¶ 9). Thus, despite the fact that the samples were sitting for up to 15 minutes before being tested, it does not mean that the samples cooled to a significant extent, as they were retained in heating mantles and not at room temperature. Ms. Kaplar further testifies that the solvent was hot when tested. *See* Second Li Declaration, dated December 6, 2010, Exhibit A (Deposition of Mary Kaplar of December 15, 2008) 91:18-19 ("A. So the fluid was hot. The TCB was hot going in."). Accordingly, the Decision did not overlook or misapprehend the details of Dr. Clough's solubility testing, and we decline to address Patent Owner's further arguments directed towards the temperature of the solubility testing. *See* Req. R'hg. 13-15.

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[3] Ms. Kaplar is said to be Dr. Clough's technician who performed the actual testing reported in Dr. Clough's Declaration. Second Li Declaration, dated December 6, 2010, ¶ 25.

Patent Owner contends that the Board overlooked Dr. Li's testimony that "[Dr. Clough's] description of the samples during testing—no swelling, no gelling, not translucent—means that Clough's testing failed to provide an accurate, let alone any, solubility result." Req. R'hg. 13 (citing Li Declaration, dated June 9, 2009, ¶ 56). As pointed out by Requester, Dr. Clough testifies that due to the high degree of crosslinking, swelling and gelling would be very minimal and not visually apparent. *See* Comments 10 (citing 2nd Clough Declaration ¶ 9; 3rd Clough Declaration ¶ 10). Dr. Li and Dr. Clough both opine as to the visual appearance and swellability/gellability of treated UHMWPE in TCB at 170°C. However, neither expert provides any underlying evidentiary support for their opinion as to the visual appearance of UHMWPE as evidence of successful solubility testing. Moreover, the '020 patent is silent as to the appearance of the treated UHMWPE during the solubility testing described in Example 3. *See* '020 patent, col. 9, l. 28 to col. 10, l. 35. We decline to credit Dr. Li's description of visual appearance over Dr. Clough's explanation to the contrary, where both lack supporting evidence that the visual appearance is indicative of the experiment's success. Accordingly, as Dr. Clough has declared personal knowledge that the steps for the solubility testing specifically recited in the '020 patent were followed, we accord the reported visual appearance of the materials during the solubility testing little, if any, probative value. *Rohm & Haas Co. v. Brotech Corp.*, 127 F.3d 1089, 1092 (Fed. Cir. 1997) ("Nothing in the rules or in our jurisprudence requires the fact finder to credit the unsupported assertions of an expert witness.").

Therefore, we decline to make any changes in the Decision mailed April 30, 2014. Accordingly, the Request for Rehearing is denied.

DENIED

alw

PATENT OWNER:

LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK
600 SOUTH AVENUE WEST
WESTFIELD, NJ 07090

THIRD-PARTY REQUESTER:

JEFF B. VOCKRODT, ESQ.
HUNTON & WILLIAMS LLP
1900 K. STREET NW, SUITE 1200
WASHINGTON, DC 20006-1109

BRYAN RUTSCH, ESQ.
KIRKLAND & ELLIS LLP
300 NORTH LaSALLE
CHICAGO, IL 60654

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LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK
600 SOUTH AVENUE WEST
WESTFIELD, NJ 07090

EXAMINER	
JASTRZAB, KRISANNE MARIE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

PTOL-90A (Rev. 04/07)

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW, INC. AND ZIMMER, INC.
Requester

v.

HOWMEDICA OSTEONICS CORP.
Patent Owner and Appellant

Appeal 2013-007710
Reexamination Control 95/000,428
Patent 6,818,020 B2
Technology Center 3900

Before MARK NAGUMO, RICHARD M. LEBOVITZ, and
RAE LYNN P. GUEST, *Administrative Patent Judges*.

GUEST, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal by the Patent Owner from the Patent Examiner's decision to reject pending claims in an *inter partes* reexamination of U.S. Patent 6,818,020 B2 (hereinafter, "the '020 patent"), which issued November 16, 2004 to Deh-Chuan Sun et al. The Board's

jurisdiction for this appeal is under 35 U.S.C. §§ 6(b), 134, and 315. We AFFIRM-IN-PART.

I. BACKGROUND

A request for *inter partes* reexamination under 35 U.S.C. §§ 311-318 and 37 C.F.R. §§ 1.902-1.997 for the ’020 patent was filed January 22, 2009 by joint Third-Party Requesters, Smith and Nephew, Inc. and Zimmer, Inc. (hereinafter jointly referred to as “Requester”). Request for *Inter Partes* Reexamination; Requester’s Respondent Brief 1, dated October 15, 2012 (hereinafter “Req. Res. Br.”). The Patent Owner is Howmedica Osteonics Corp. Patent Owner Appeal Br. 1, dated May 18, 2012 (hereinafter “App. Br.”). Claims 1-12 are pending and stand rejected. An oral hearing was held October 30, 2013. A transcript of the hearing was entered into the record.

The ’020 patent is the subject of a pending litigation in the District of New Jersey styled *Howmedica Osteonics Corp.* v. *Zimmer, Inc., et al.,* No. 2:05-cv-00897-WHW. This litigation is stayed pending the outcome of this reexamination proceeding. App. Br. 1; Req. Res. Br. 1.

The ’020 patent issued from U.S. Application No. 10/461,636 on November 16, 2004. The ’020 patent claims priority through a chain of continuation and divisional applications to U.S. Application No. 08/070,074 filed June 1, 1993, now U.S. Patent 5,414,049. The ’020 patent thus expired June 1, 2013, 20 years from the earliest filed application date.

The’020 patent is directed to an ultra-high molecular weight polyethylene (UHMWPE) medical implant with good oxidation resistance

upon irradiation. ’020 patent, col. 1, ll. 20-24; col. 3, ll. 35-37. Upon application of sterilizing radiation to the implant, free radicals are formed (arising from C-C chain scission or C-H scission (*id*. at col. 2, l. 5)), which cause UHMWPE to become activated for chemical reactions and physical changes, making the resulting implant susceptible to oxidation. *Id.*, col. 3, ll. 45-51. Although some polymer free radicals may recombine soon after irradiation, others may persist, resulting in degradation of polymer properties over time. *Id*. at col. 3, ll. 1-11. The’020 patent describes a process in which a UHMWPE is irradiated under inert conditions and subsequently annealed to cross-link all the free radicals without employing “stabilizers, oxidants, or any other chemical compounds which may have potential adverse effects in biomedical or orthopedic applications.” *Id.* col. 3, ll. 54-47. As a result, the UHMWPE is said to become cross-linked and to have an oxidation resistance “similar to that of the unirradiated virgin polymer.” *Id*. at col. 3, l. 65-col. 4, l. 7.

The claims of the ’020 patent are directed to a medical implant comprising an irradiated UHMWPE, having a weight average molecular weight greater than 400,000,[1] which has at least one of the following additional properties:

a) a solubility of less than 80.9% in trichlorobenzene (claims 1, 7, and 11), more particularly 1,2,4-trichlorobenzene (claim 5);
b) the level of free radicals in the polyethylene is $1x10^{17}$/gram or less (claims 2, 6, and 10);

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[1] This is a special definition. A polyethylene is generally considered a UHMWPE when it has a molecular weight exceeding 1.7-2.5 million. *See* Lue, p. 16; Li Supp. Decl. ¶ 50; Pruitt Supp. Decl. ¶ 40.

c) a FTIR (Fourier Transform Infra-red Spectroscopy[2]) oxidation index which does not increase with oven aging in air at 80° C for up to 11 days (claims 3, 6, 7, 10, 11, and 12) or up to 23 days (claims 4 and 8);

d) FTIR oxidation index of 0.01 (claim 11) or less (claim 12).

App. Br., Claim App'x.

Patent Owner appeals the Examiner's decision to reject the claims under 35 U.S.C. § 102 and § 103. The grounds of rejection are discussed separately below as necessary.

II. Claims 1-6

ANTICIPATION BY LUE

Claims 1-6 stand rejected as anticipated under 35 U.S.C. § 102(b) over Lue[3] as evidenced by the Clough Declaration[4] and the Wang references.[5] RAN 3.

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[2] Patent Owner's recitation of the claims states that FTIR means "Fourier Transform *Below-red* Spectroscopy" (App. Br., Claim App'x)(emphasis added), but the original claims of the '020 patent, which were not amended during this reexamination proceeding, states that FTIR means "Fourier Transform *Infra-red* Spectroscopy". '020 patent, col. 12, ll. 9-10.

[3] Ching-Tai Lue, "Effects of Gamma Irradiation and Post Heat Treatments on the Structure and Mechanical Properties of Ultra High Molecular Weight Polyethylene (UHMW-PE)," Masters Thesis, University of Lowell, 1979 (hereinafter referred to as "Lue").

[4] First Declaration of Roger L. Clough, dated January 16, 2009, and made of record as Appendix B to the Request on January 22, 2009 (hereinafter "Clough Declaration" or "Clough Decl."). The Clough Declaration is further supported by additional testimony of Dr. Clough in the Second Clough Declaration, dated July 9, 2009, and made of record on the same date with Requester's Comments (hereinafter "2nd Clough Declaration" or "2nd Clough Decl."), and in the Third Clough Declaration, dated January 1,

Independent claim 1 states "A medical implant comprising an irradiated ultra-high molecular weight polyethylene having a weight average molecular weight greater than 400,000 and a solubility of less than 80.9% in trichlorobenzene." Claims 1-5 depend from claim 1.

Independent claim 6 states "A medical implant comprising an irradiated ultra-high molecular weight polyethylene having a weight average molecular weight greater than 400,000 wherein the level of free radicals is $1x10^{17}$/gram or less and an oxidation index which does not increase during oven aging in air at 80° C for 11 days."

While many of the arguments presented in this case are directed to the solubility property recited in claim 1, Patent Owner separately argues that the prior art does not teach the additional properties recited in dependent claims 2-4 and 6. App. Br. 15-17. We consider how the evidence of record affects each of the recited properties of claims 1-6 separately, but discuss the evidence of record with respect to each of the properties together for brevity.

2011, and made of record on January 5, 2011 with Requester's Comments (hereinafter "3rd Clough Declaration" or "3rd Clough Decl.").

[5] Wang A, et al., "Effects of Sterilization Methods on the Wear of Ultra-High Molecular Weight Polyethylene Acetabular Cups," 5th World Biomaterials Congress, Abstract No. 275, May 28-June 2, 1996, Toronto, Canada (hereinafter referred to as "Wang I"). Wang et al., "Effects of Sterilization Methods on the Wear of Ultra-High Molecular Weight Polyethylene Acetabular Cups," 5th World Biomaterials Congress, Toronto, Canada (1996) (hereinafter referred to as "Wang II"). Sun et al., "Development of Stabilized UHMWPE Implants with Improved Oxidation Resistance via Crosslinking," 63rd Annual Meeting of the AAOS, Feb. 22-26, 1996, Atlanta, Georgia (hereinafter referred to as "Wang III"). Wang I, Wang II, and Wang III are collectively referred to as the "Wang references." We note that the inventors of the '020 patent, Deh Chuan Sun and Casper F. Stark, are also authors on each of the Wang references.

It is undisputed that Lue describes UHMWPE that has been irradiated in an inert atmosphere and heat treated at 150°C for one hour. RAN 3; Lue, p. 56. Lue does not teach all the properties recited in the claims. For example, the Examiner finds that Lue describes the solubility range in xylene for UHMWPE irradiated in air and in nitrogen, but not in trichlorobenzene. RAN 4; Lue, p. 58-60 and 78, Table IX.

A claim may be anticipated if an element, although not explicitly described, is inherent in a prior art disclosure. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999). "Inherency ... may not be established by probabilities or possibilities." *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981).

In a case such as this where patentability rests upon a property of the claimed material not disclosed within the art, the PTO has no reasonable method of determining whether there is, in fact, a patentable difference between the prior art materials and the claimed material. Therefore, where the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily possess the characteristics of his claimed product. *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990); *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977).

When the Examiner relies upon a theory of inherency, the Patent Office must show a "reason to believe" that a property "asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art." *In re Swinehart*, 439 F.2d 210, 212-13 (Fed. Cir. 1971); *Best*, 562 F.2d at 1254-1255.

The Requester puts forth three rationales for finding that Lue inherently teaches an irradiated UHMWPE having the solubility, oxidation index, and free radical properties recited in the claims. Patent Owner contends that Lue does not teach a UHMWPE having the solubility, free radical or oxidation index properties recited in the claims and that none of the Requester's three inherency positions is sufficient for a finding that the recited claim properties are anticipated. App. Br. 6-17. For the reasons that follow, we find only the third rationale persuasive.

Rationale #1: *"general rule"*

The first rationale proposed by Requester is that, because Lue discloses the same materials, the same irradiation process, and an annealing process that provides equivalent heat, the properties of the UHMWPE of Lue are inherently the same as those described in the '020 patent. Req. Res. Br. 3-5.

Requester argues that Lue's annealing step of 150°C for 1 hour would produce equivalent heat to the annealing step described in the '020 patent of 50°C for 144 hours. *Id.* at 5. Requester contends that it is a general rule that "for every 10°C increase (or decrease) in temperature, the time required for equivalent heating is cut in half (or doubled), respectively." Req. Res. Br. 4, n. 3.[6]

The '020 patent teaches that free radicals are eliminated by annealing, giving rising to an oxidation index meeting the requirement recited in some

[6] According to Requester, this "general rule" was first put forth by Patent Owner in a concurrent litigation. *Id.* at 4.

of the dependent claims (col. 5, ll. 25-35). Based on experiments using an annealing step at 50°C for 144 hours, the ’020 patent demonstrated oxidation index and solubility meeting limits recited in the claims (col. 7, l. 51-col. 10, l. 35, Examples 1 and 3). However, the claims are not limited to an annealing step taking place precisely at this temperature and length of time. The ’020 patent describes that

> Compared to room temperature, an elevated temperature . . . helps free radicals . . . to migrate in the plastic matrix to meet other neighboring free radicals for cross linking reactions. In general, the desired elevated temperature is between the room temperature and the melting point of the polymer. For UHMWPE, this temperature range is between about 25° C. and about 140 °C. However, the preferred annealing temperature range is from about 37° C. to about 135° C. The preferred time and temperature is 130° C. for 20 hours with *the minimum annealing time being about 4 hours (requiring a temperature at the high end of the range)*. It is to be noted that the higher the temperature used, the shorter the time period needed to combine free radicals.

’020 patent, col. 5, ll. 38-51 (emphasis added).[7]

Nonetheless, the ’020 patent does state a minimum annealing time of 4 hours at the high end of the temperature range, and only describes solubility and non-increasing oxidation index properties for examples that were annealed at 50° C for 144 hours. *Id.*, col. 7, l. 20 to col. 10, l. 35 (particular Examples 1 and 3). Based on the ’020 patent, the claimed solubility and oxidation index would not have been considered inherent in a

[7] *See also* ’020 patent, col. 6, ll. 36-47 (“In general, if a higher temperature is used, a shorter time period is required to achieve a prescribed level of oxidation resistance and cross-linking.”).

prior art reference teaching an annealing step at a time less than 4 hours or at a time and temperature that was not substantially identical to 50 °C for 144 hours. Thus, annealing at 150 °C for 1 hour taught by Lue is insufficient evidence to presume that claimed solubility and oxidation index would necessarily be as recited in any of the claims without additional evidence.

The Examiner does not appear to have adopted this rationale (RAN 5-6 and 27-38), and we do not find this rationale to be persuasive. Requester has not directed us to any factual support for the validity of application of the "general rule" to irradiated UHMWPE, and has not shown that providing "equivalent heating" would necessarily result in a UHMWPE implant having the recited properties.[8]

Rationale #2: The Wang references

The second rationale proposed by Requester and adopted by the Examiner is that the Wang references provide evidence that Lue inherently teaches the recited solubility in trichlorobenzene. RAN 3-5 and 30-31.[9]

Wang I describes processes in which (a) UHMWPE was irradiated in air and (b) UHMWPE was irradiated in nitrogen and stabilized at 50°C for six days (144 hours) ("inert radiation"). Wang I, p. 2, col. 1, 2nd ¶. Wang I states that the percentage of insolubles (gel content) was measured in trichlorobenzene at 170°C and in xylene at 140°C. *Id*., col. 2, 2nd ¶.

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[8] For example, Requester has not addressed the fact that UHMWPE has a melting point of about 140°C. Accordingly, the application of the "general rule" may not, in fact, produce equivalent heat above 140°C.

[9] The Wang references are not prior art under 35 U.S.C. § 102 and are only relied upon as evidence of what is inherently taught by Lue and Streicher. *See* Request 30, n. 5.

Wang II describes a process in which UHMWPE is irradiated in air. Wang II, p. 198, col. 1, 2nd ¶. Wang II states that the percentage of insolubles (gel content) was determined by "a high temperature solvent extraction method" and cites to U.S. Patent 5,414,049.[10] *Id.*, 3rd ¶ and n. 4. However, Wang II does not describe the solvent used and we cannot presume the solvent described is trichlorobenzene as described in the '049 patent. Further, Wang II does not describe a process in which UHMWPE is irradiated in an inert environment or describe heat-stabilization of irradiated UHMWPE.

Wang III describes processes in which (a) UHMWPE was irradiated in air and (b) UHMWPE was irradiated in inert gas under vacuum and stabilized by the method described in U.S. Patent 5,414,049 (which is substantially the same disclosure as the '020 patent). Wang III, p. 2, col. 1, 1st and 2nd ¶¶. Wang III describes measuring the percentage of insolubles (gel content) in trichlorobenzene. *Id.*, col. 2, 2nd ¶.

The solubilities[11] reported in the Wang references are charted below:

	Wang I TCB[12] and xylene	Wang II solvent not disclosed	Wang III TCB
Air irradiation	40-55%	40-55%	54%
Inert irradiation	5-25%		25%

[10] U.S. Patent 5,414,049 and the '020 patent have substantially similar disclosures describing measuring solubility of irradiated and annealed UHMWPE in hot 1,2,4-trichlorobenzene. *See* col. 9, l. 59-col. 10, l. 64.
[11] We calculate the solubility as the reverse of the reported percentage of insolubles (gel content). App. Br. 14, n. 3; 3rd Clough Decl. ¶ 21. Thus, Wang II reports a gel content of 45-60% for air irradiated UHMWPE and 75-95% for inert radiated and stabilized UHMWPE.

and stabilized			

Because the insolubles were within the same reported ranges, the Examiner determined that the solubility of UHMWPE in xylene at 140°C and in trichlorobenzene at 170°C are equivalent, and, thus, the solubility measurement reported by Lue for irradiated UHMWPE in xylene at 135°C would have been substantially the same for trichlorobenzene at 170°C. RAN 30-31.

We disagree with the Examiner that the Wang references provide sufficient evidence that the solubility of UHMWPE in xylene at 140°C and in trichlorobenzene at 170°C are equivalent in order to properly to shift the burden to Patent Owner to demonstrate otherwise. For example, Wang I, the only one of the Wang references that states that gel content was measured in both xylene and trichlorobenzene, provides a range of solubility of 40-55% (air-irradiated) and 5-25% (irradiated under nitrogen and stabilized). Wang I does not state where within this range particular data for xylene and particular data for trichlorobenzene fall. Nor does Wang I state that the results for the two solvents differ or are the same. Since Wang III reports solubility for trichlorobenzene only at the higher end of the range of Wang I, namely 54% and 25%, respectively, one might also conclude that the lower end of Wang I reflects solubility in xylene while the higher end reflects solubility in trichlorobenzene. The fact that Wang II reports a similar range of solubility to that of Wang I of 40-55% but is silent as to the solvent used,[13] and, thus, fails to clarify the range reported in Wang I. Thus, from

[13] As noted above, the citation to the '049 patent may suggest the solvent used was trichlorobenzene. However, without a discussion in the reference of the solvent such a conclusion is speculative. If the solvent were

the Wang references alone, there is insufficient evidence of xylene and trichlorobenzene equivalency, as the data may alternatively demonstrate a difference in solubility of up to 15%. Nor are we persuaded that the Wang references demonstrate any particular correlation between solubility in xylene and solubility in trichlorobenzene.

Further, it is undisputed that Wang I and Wang III, the references that describe a "stabilizing" step in addition to irradiation, describe a process similar to that of the '020 patent, which differs from the teachings of Lue regarding times and temperatures for annealing. Accordingly, the Wang references have not been shown to speak to the results of the process described in Lue.

Notwithstanding this determination, we are not persuaded by Patent Owner's argument that the Wang references, in fact, reported only the solubility measurements for xylene. App. Br. 7-11. In support of this argument, Patent Owner relies on Wang IV,[14] the Wang Declaration,[15] and the First Li Declaration and Supplemental Li Declaration.[16] *Id.*

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trichlorobenzene then the source of the variability between Wang II and III is not explained.

[14] V. Krishna Polineni, et al., "Effect of Gamma-Radiation Induced Oxidation and Crosslinking on the Wear Performance of Ultra-High Molecular Weight Polyethylene (UHMWPE) Acetabular Cups," Reprint from Standard Technical Publication 1307, Am. Soc. For Testing and Materials, pp. 95-108 (1998) (hereinafter "Wang IV").

[15] Declaration of Dr. Aiguo Wang, dated December 1, 2010, and entered into the record on December 6, 2010, with Patent Owner's Response (hereinafter "Wang Declaration" or "Wang Decl.").

[16] Declaration of Dr. Stephen Li, dated June 9, 2009 and entered into the record the same date with Patent Owner's response (hereinafter "First Li Declaration" or "1st Li Decl.") and Declaration of Dr. Stephen Li, dated

Wang IV describes processes in which (a) UHMWPE was irradiated in air and (b) UHMWPE was irradiated in nitrogen and stabilized at 50°C for 144 hours. Wang IV, p. 97-98. Wang IV reports that the percentage of insolubles (gel content) were determined in xylene at 140°C for 24 hours according to an ASTM test (D 2765-90).[17] *Id*., p. 98, last ¶. Wang IV (para. bridging 101-102) reports an air irradiated UHMWPE solubility of 55% in xylene and a stabilized UHMWPE solubility of 25% in xylene, which is substantially identical with the gel contents for trichlorobenzene reported in Wang III and thus supports, rather than contradicts, the Examiner's position regarding equivalency.[18]

Dr. Wang is one of the authors of the Wang references and Wang IV. Wang Decl. ¶ 6 and 9. Dr. Wang is currently an employee of the Patent Owner and was at time of the publication of the Wang references and Wang IV. *Id.* ¶ 2. Dr. Wang testifies that he has "no actual recollection as to whether the solubility data reported in the three 1996 Wang references was obtained using the trichlorobenzene test method disclosed in the '020 patent." *Id.* ¶ 7. Dr. Wang "doubt[s]" that the tests of the Wang references were in trichlorobenzene because (a) Howmedica at the time used only

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December 6, 2010, and entered into the record on the same date with Patent Owner's Response (hereinafter "Supplemental Li Declaration" or "Li Supp. Decl.").

[17] This particular standard method for testing solubility uses xylene as a solvent. *See* Request for *Inter Partes* Reexamination 17 and Exhibit 7.

[18] We note that neither the Examiner nor the Requester rely on Wang IV in rejecting the claims as being anticipated. Nonetheless, since Wang IV reports xylene gel content at the lower end of the range described in Wang II, Wang IV also further confuses rather than clarifies the range reported in Wang II.

xylene for in-house testing, and "we would typically have reported solubility results determined by in-house testing" (b) "Wang IV discloses virtually the same solubility test results as in Wang I-III for UHMWPE materials processed in the same way," and (c) trichlorobenzene is a relatively more aggressive solvent for UHMWPE and solubility in trichlorobenzene will differ from solubility in xylene. Wang Decl. ¶¶ 7-10.

Dr. Wang's testimony is not persuasive as it is conclusory and lacking in evidentiary support. Dr. Wang's lack of recollection and report of "typical" practice are not probative of what the Wang references teach to persons skilled in the art; nor are they probative of the range of options available to researchers at Howmedica during the periods relevant to this appeal. In this regard, we find the testimony of Mark Jordi, that Howmedica outsourced TCB solubility testing during the relevant period undercuts Dr. Wang's credibility. We note the unexplained absence of supporting documentation regarding a critical issue in the case in light of the report in the '020 patent that solubility tests were conducted in TCB.

In the absence of further information from the inventors and authors, it was reasonable for the Examiner to conclude that the reports of the Wang references may be accepted at face value, though not conclusive as to equivalency of the solvents as discussed above.

Finally, neither the Requestor nor the Patent Owner has directed our attention to a direct comparison of the solubility of TCB and xylene on the same sample of UHMWPE. Dr. Wang's testimony that TCB is a relatively more aggressive solvent than xylene is not supported by direct evidence, and we have not been provided with a reasoned explanation of what a person

having ordinary skill in the art would have expected the magnitude of the differences in solubility, if any, to be.

Dr. Li testifies that he has extensive experience in using UHMWPE as a material in medical devices included joint replacement. 1st Li Decl. ¶¶ 3-7 and 10. He has consulted for over 10 years with companies in the research, development and testing of material, including UHMWPE used as bearing surfaces in joint replacement. *Id.* ¶ 5. We find Dr. Li qualified to testify as to research and development involved in using UHMWPE in joint replacement.

Dr. Li testifies that the results of the Wang reference do not accurately reflect solubility of measurements in trichlorobenzene but are consistent with measurements taken in xylene. 1st Li Decl. ¶ 63-64. In support of this position, Dr. Li relies on the discrepancy between the results reported in the ’020 patent for trichlorobenzene and in Wang IV for xylene. 1st Li Decl. ¶ 64. Dr. Li also relies on personally conducted testing of GUR 1050 UHMWPE that was irradiated in air and nitrogen in accordance with the solubility test method of the ’020 patent in trichlorobenzene. Li Supp. Decl. ¶¶ 6-15. Dr. Li reported solubility of greater than 100% in each case, with one test result of 95.8% being the exception. *Id.* Dr. Li then compared this solubility testing with the results reported in the ’020 patent, Wang IV, and solubility testing data from “several years ago” for UHMWPE in xylene. *Id.* at 16-24. Dr. Li reports the data as follows. *Id.* ¶ 21. The following table is reproduced from page 5 of Dr. Li’s supplemental declaration (dated Dec. 6, 2010):

	Xylene Solubility		TCB Solubility	
UHMWPE Sample	Dr. Li	Wang IV	'020 Patent	Dr. Li
Unirradiated	72.4%, 99%, 82.6%, 78.7%	90%	--	100.1%, 100.1%
Air-irradiated at 2.5 Mrad	7.8%; 8.1%	55%	98.2%	100.1%, 102.5%
Nitrogen – irradiated at 2.5 Mrad, nominal	--	--	--	100.2%, 100.2%, 100.4%, 95.8%
Nitrogen irradiated and annealed at 50°C for 144 hours	--	25%	80.9%	--

Dr. Li concludes that "the solubility of UHMWPE materials in TCB and xylene can vary from 1% to 92.2%." *Id.* ¶¶ 20-21.

We do not find Dr. Li's data to be persuasive. The distinctions between Dr. Li's solubility results and those of Wang IV and the '020 patent raise questions as to the whether the testing was of identically irradiated UHMWPE and subsequently identically treated samples in xylene and trichlorobenzene so as to demonstrate a distinction in the results. Similarly, Dr. Li's results for air-irradiated, but not annealed, UHMWPE in xylene is not consistent with Wang IV's results which may reflect variability between the UHMWPE samples tested or other unexplained variables. Moreover, Dr. Li does not provide xylene solubility testing data for any samples irradiated in an inert environment for consistent comparison with his results in TCB.

Dr. Li further testifies that the "two solvents differ in strength for dissolving UHMWPE." Li Supp. Decl. ¶ 22; *see also* 1st Li Decl. ¶¶ 24-27. Similar testimony by Dr. Wang, supra, is further supported by the testimony of Dr. Pruitt.[19] Pruitt Supp. Decl. ¶ 20 ("[P]ersons of ordinary skill cannot

[19] Declaration of Dr. Lisa Pruitt, dated June 9, 2009 and entered into the record the same date with Patent Owner's response (hereinafter "1st Pruitt

accurately correlate or predict solubility in TCB from a known solubility in xylene.") (commenting on Dr. Li's solubility Table (Li ¶ 21); *see also* 1st Pruitt Decl. ¶ 29-32 (substantially identical testimony to 1st Li Decl. ¶¶ 24-27). Dr. Pruitt has 16 years of teaching experience in material science, including conducting specific research on the effects of sterilization, aging, and crosslinking of UHMWPE. 1st Pruitt Decl. ¶¶ 14-15. We find Dr. Pruitt qualified to testify as to the effects of sterilization, aging and crosslinking of UHMWPE.

We find this general testimony that there is in fact a difference in the two solvents to be persuasive by preponderance of the evidence based on the technical expertise of Dr. Li and Dr. Pruitt and the inconsistencies between the Wang publications, suggesting that xylene and trichlorobenzene have different solubility for UHMWPE.

Rationale #3: The Clough Declaration

The third rationale supporting Lue's anticipation by inherency is that the Clough Declaration shows that the procedure used in Lue does, by the preponderance of the evidence, have the solubility, oxidation index and free radical properties recited in the claims. RAN 3-4; Req. Res. Br. 6-8.

Dr. Clough testifies to having 30 years of experience studying the radiation effects of polymers on oxidation and stability. Clough Decl. ¶ 3. Dr. Clough testifies that he obtained two different resin types of UHMWPE,

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Declaration" or "1st Pruitt Decl.") and Supplemental Declaration of Dr. Lisa Pruitt, dated December 6, 2010 and entered into the record on the same date with Patent Owner's Response (hereinafter "Supplemental Pruitt Declaration" or "Pruitt Supp. Decl.").

GUR 4030 and GUR 4130, in three different manufacturing lots. *Id.*, ¶ 22. Dr. Clough testifies further that he prepared a detailed protocol for reproducing the irradiation and heating procedures set forth in Lue on GUR 4030 and GUR 4130 UHMWPE samples. *Id.*, ¶¶ 21-34 and Exhibit 2. Dr. Clough testifies further that he set up protocols to measure the treated UHMWPE for solubility and FTIR oxidation index at 80°C after 11 days. *Id.*, ¶¶ 29-30. Dr. Clough also ordered the testing of the level of free radicals in the resulting UHMWPE samples. *Id.*, ¶¶ 34. Dr. Clough testifies that the protocols were followed for twelve samples from each lot, and that the resulting solubility, FTIR oxidation index at 80°C after 11 days, and level of free radicals all fall within the ranges recited in the claims. *Id.*, ¶¶ 29, 33, and 34. We have reviewed the protocols as well as the specific results for each of the twelve samples from each lot and find them to be the most detailed data presented in the record. *Id.* Exhibits 2-12.

Patent Owner argues that because Lue does not describe surgical grade UHMWPE, that Lue does not teach "a medical implant" as recited in the claims. App. Br. 17. Patent Owner's argument is not persuasive. Lue describes using UHMWPE in orthopedic devices and thus teaches a medical implant. *See* Lue, Abstract and p. 52. We disagree that the recitation in the preamble of a "medical implant" structurally defines the UHMWPE otherwise recited in the claims. "[A] claim preamble has the import that the claim as a whole suggests for it." *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620 (Fed. Cir. 1995); *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997) ("[W]here a patentee defines a structurally complete invention in the claim body and uses the preamble only

to state a purpose or intended use for the invention, the preamble is not a claim limitation.”). On the present record, the term “medical implant” only imports that a UHMWPE is suitable as a medical implant if it has the properties claimed.

Patent Owner also argues that, since Lue did not disclose a type or grade of UHMWPE, and the GUR 4030 and GUR 4130 UHMWPE used by Dr. Clough may not have been the same UHMWPE samples taught by Lue. App. Br. 11-13. Patent Owner argues that Dr. Clough could have copied the testing procedures of Lue to demonstrate similarity of material, but did not. *Id.* Patent Owner further argues that inherency can only be established on evidence that is “substantially identical” to the asserted prior art and that the evidence is insufficient if it fills in gaps in the disclosure with mere guesses. *Id.*; Req. Res. Br. 7-10.

We disagree with Patent Owner that Dr. Clough’s use of GUR 4030 and GUR 4130 UHMWPE discredits the results he provides. Lue was silent as to the type or grade of UHMWPE treated according to the process that he discloses. We find that Dr. Clough took reasonable steps to find similar UHMWPE to that available at the time of Lue. Clough Decl. ¶¶ 23-26. Accordingly, we find that the materials used by Dr. Clough to be sufficiently similar to those used at the time of Lue to shift the burden to Patent Owner to show that such differences are significant. Patent Owner has directed us to no persuasive evidence to show that particular resins or grade used by Dr. Clough would have created a significant difference in Dr. Clough’s results.

Patent Owner further argues that Dr. Cough did not perform a proper “hot filtered” solubility test for trichlorobenzene as recited in the ’020

patent. App. Br. 13-15; Req. Res. Br. 10-13. In this case, Patent Owner relies on the testimony of Dr. Li, Dr. Pruitt, and Dr. Jordi as evidence that one of ordinary skill in the art would have understood the term “hot filtered” in the ’020 patent to require both a hot filter and a hot filtrate. App. Br. 13.

Dr. Clough testifies that hot filtration was accomplished using a high temperature 400-mesh wire filter 0.001” thick (weighing about 0.8 g), placed between two glass funnels, with the upper glass funnel preheated to 170°C. The trichlorobenzene solution (150 ml), which was also at 170°C, was then filtered. Dr. Clough testifies that the filter was not separately heated. Second Clough Declaration ¶¶ 5-6, dated July 9, 2009, and Third Clough Declaration ¶¶ 6, 8, and 9, dated January 1, 2011. The mass of the undissolved polymer remaining on the filter was determined by subtracting the mass of the filter from the mass of the filter and the mass of the undissolved polymer following washing with methylene chloride and drying according to the protocol (Exhibit 3) for each of twelve samples in two lots (Exhibits 5 and 6). The solubility results range from 0.7% (sample 11A) to 2.8% (sample 4A), with an average of 1.6% (Exhibit 5), and from 1.6% (sample 9D) to 5.0% (Examples 6 and 11D), with an average of 2.7% (Exhibit 6.)

Dr. Li reports conducting solubility testing of similarly irradiated UHMWPE in trichlorobenzene with (a) a “Hot Filter, Hot Filtrate” and (b) a “Hot Filter, Cooled Filtrate” and (c) a “Cold Filter, Cooled Filtrate”. Li Supp. Decl. ¶ 28, Table. The particular materials used are not identified by source and lot number, nor is the testing protocol (what was measured under what conditions, how the reported solubility was calculated) presented in

detail. Dr. Li does state that the "cooled/cold filtrate was obtained by allowing the filtrate to stand at room temperature for about 10-15 minutes before it was filtered." *Id.*, ¶ 28.

Dr. Li has not directed our attention to any indications that the data presented by Dr. Clough for the twelve samples reported in each test reflect the effect of systematic cooling. As Dr. Clough points out,

> If Drs. Li and Pruitt's assumption that the sample solutions were cooling down while waiting to be filtered was accurate, then one would expect a downward trend in solubility data between one filtration to the next (because under their theory, as time passed and the samples cooled, each sample would show lower solubility due to the precipitation of the solute.)

Third Clough Declaration, ¶ 9. No such trend, however, is evident in Clough's data. *See* Clough Decl., Exhibits 5 and 6.

We do not find Dr. Li's evidence persuasive that Dr. Clough's use of a cold filter made a substantial difference to the outcome of his solubility results. Dr. Li's data did not show that the temperature of the filter was the critical factor, for example, by comparing using hot and cold filters with high temperature filtrate.

Further, Dr. Li's described protocol suggests that his "Cooled Filtrate" was identical to Dr. Clough's "Cooled Filtrate," which is not supported by Dr. Clough's testimony that the filtrate was not cooled, but was still 170°C. *See* Third Clough Declaration ¶ 9 ("We did not allow the solutions to cool, and the samples were filtered at approximately 170°C.").[20]

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[20] Dr. Clough testifies that the samples were kept in insulating heating mantles (Third Clough Declaration ¶ 8), not left at room temperature per Dr. Li's "Cooled/cold filtrate" protocol. Li Supp. Decl. ¶ 28.

Dr. Li testifies that solubilized UHMWPE would precipitate out of solution when the temperature falls below 140°C (Li Supp. Decl. ¶ 27, but Dr. Clough testifies that his solution was filtered at 170°C and Dr. Li directs us to no evidence to indicate that Dr. Clough's solution fell below 140°C.

Accordingly, Patent Owner has not persuasively shown that the solubility test performed by Dr. Clough was substantially different such that we could not consider his data as probative of the inherent solubility of Lue's treated UHMWPE.

Patent Owner has not presented any persuasive evidence disputing the results obtained by Dr. Clough regarding level of free radicals or FTIR oxidation index.

For these reasons, we find that Dr. Clough's data provides a basis in fact and/or technical reasoning to reasonably support the determination that the properties recited in the claims necessarily were present in the UHMWPE samples treated as described in Lue. Accordingly, a finding of inherency is reasonable, and the burden shifts to Patent Owner to show otherwise. Patent Owner presented no persuasive evidence that UHMWPE treated according to Lue's irradiation and annealing procedure does not have the properties recited in the claims.

We affirm the Examiner's rejection of claims 1-6 as being anticipated by Lue.

ADDITIONAL REJECTIONS OF CLAIMS 1-6

In affirming the rejection of claims 1-6 as anticipated by Lue, it is unnecessary to address the additional rejections maintained by the Examiner

for claims 1-6. *See In re Gleave*, 560 F.3d 1331, 1338 (Fed. Cir. 2009) (holding that obviousness rejections need not be reached upon affirming a rejection of all claims as anticipated).

II. Claims 7-12

Independent claim 7 recites "A medical implant comprising an ultra-high molecular weight polyethylene having a weight average molecular weight greater than 400,000 irradiated and annealed at temperature greater than 25 C. for a sufficient time to have a solubility of less than 80.9% in trichlorobenzene and a non-increasing FTIR oxidation index during oven aging in air at 80° C for up to 11 days."

Patent Owner does not separately argue any of the claims 7-12. App. Br. 30-31 and 33-35. We consider how the evidence of record affects each of the recited properties of claims 7-12 separately, but discuss the evidence of record with respect to each of the properties together for brevity.

Claims 7-12 include the further limitation that the UHMWPE is "annealed at a temperature greater than 25° C." The '020 patent has expired and may no longer be amended.

> While claims are generally given their broadest possible scope during prosecution, *In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000), the Board's review of the claims of an expired patent is similar to that of a district court's review, *Ex parte Papst-Motoren*, 1 U.S.P.Q.2d 1655, 1655-56 (B.P.A.I. Dec. 23, 1986); *see also* MPEP § 2258.I.G. (directing Examiners to construe claims pursuant to *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc), during reexamination of an expired patent).

In re Rambus Inc., 694 F.3d 42, 46 (Fed. Cir. 2012). We have held:

> [I]n reexamination proceedings in which the PTO is considering the patentability of claims of an expired patent which are not subject to amendment, a policy of liberal claim construction may properly and should be applied. Such a policy favors a construction of a patent claim that will render it valid, i.e., a narrow construction, over a broad construction that would render it invalid.

Papst-Motoren, 1 USPQ2d at 1656. "In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips v. AWH Corp.*, 415 F3d. 1303, 1312-17 (Fed. Cir. 2005)). Importantly, it is "error ... to use the possible invalidity of those claims, if broadly construed, as a basis for construing them narrowly." *The Saunders Group, Inc. v. ComforTrac, Inc.*, 492 F.3d 1326, 1335 (Fed. Cir. 2007); *Phillips*, 415 F.3d at 1327 ("[W]e have certainly not endorsed a regime in which validity analysis is a regular component of claim construction.").

The Examiner interpreted the language of claims 7-12 consistent with the District Court of New Jersey to mean "annealed at a temperature of greater than 25°C and less than the melting point of that material, approximately 140°C." RAN 9. Because the claims use the word anneal, the District Court found that the '020 patent limited an "annealing" process to a "temperature range [that] is between about 25° C. and about 140° C." *Howmedica Osteonics Corp.* v. *Zimmer, Inc., et al.,* No. 2:05-cv-00897-WHW, *Markman* Order 28-29, dated April 23, 2007 (Request, Exhibit 2); *see*'020 patent, col. 5, ll. 44-45 and col. 6, ll. 48-51.

While Requester argues that the District Court's interpretation is not the broadest reasonable interpretation (Req. Res. Br. 13, n. 10), Requester has not explained why a different interpretation of the term "annealed" should be used in this proceeding or that we should apply a substantively broader interpretation considering the fact that the '020 patent is expired. We find that the Examiner's interpretation is consistent with the Specification which states that "the temperature should not exceed the distortion temperature of either the packaging material or the plastic components. For UHMWPE, the temperature range is between about 25° C. and about 140° C." '020 patent, col. 6, ll. 48-51. Accordingly, we determine that it was reasonable for the Examiner to apply an interpretation of claims 7-12 that requires UHMWPE that is "annealed at a temperature of greater than 25°C and less than the melting point of that material, approximately 140°C."

OBVIOUSNESS OVER LUE AND LAWTON

Lue discloses annealing at 150°C and not at a temperature below 140°C. RAN 9; Req. Res. Br. 13. However, the Examiner finds that Lawton discloses "annealing irradiated HD polyethylenes below the melting point thereof in order to render the polyethylene products amorphous without allowing the products to lose shape" and determines that "[i]t would have been obvious to one of ordinary skill in the art to utilize temperatures below the melting point in the heating step in Lue in order to minimize oxidative degradation of the product while maintaining the product shape." RAN 9.

Patent Owner argues, *inter alia*, that even the combined teachings of Lue and Lawton fail to disclose the claimed solubility, oxidation index, and level of free radicals and that "it is unrealistic that incorporating the heating of Lawton '897 into Lue would result in the claimed properties." App. Br. 34-35.

Lawton discloses annealing HDPE post irradiation "at from about 90° C. (i.e., 85-95° C.) to just below its melting point so as to render it substantially amorphous without allowing the irradiated product to lose its shape" (Lawton, col. 7, ll. 63-67) and specifically heats at 130 °C for 6 minutes. *Id.*, col. 3, ll. 44-47.

As we discussed, *supra*, the Clough declaration provided a basis in fact and/or technical reasoning to reasonably support the determination that annealing at 150° C for 1 hour in the process of Lue necessarily produced the claimed properties and shifted the burden to Patent Owner to show otherwise. However, neither the Examiner nor the Requester has provided a basis in fact and/or technical reasoning to reasonably support the determination that annealing at a lower temperature at a time less than 4 hours necessarily produces the claimed properties or, alternatively, that the claimed properties would have been obvious otherwise.

The Requester and the Examiner point out that Lue further describes "slow cooling" after annealing for 5 hours to room temperature. RAN 36; Req. Res. Br. 14. However, the mere reliance on 5 hours of cooling, presumably with lower and lower temperatures as it cools, is not sufficient to support a finding that the claimed properties are inherent or persuasive that the claimed properties are otherwise obvious to the skilled artisan.

Accordingly, the Examiner erred in determining that a UHMWPE having the claimed properties would have been obvious to one of ordinary skill in the art based on the teachings of Lue and Lawton.

ADDITIONAL REJECTIONS OF CLAIMS 7-12

The additional rejections of claims 7-12 maintained by the Examiner include the rejection based on Dole ’83 in view of De Boer and Lawton and the rejection based on Oonishi, Masuda, Dole ’83, Dole ’79 and Lawton.

These rejections fail for the same reasons discussed above with respect to applying a lower temperature to the teachings of Lue. Neither the Requester nor the Examiner has provided a basis in fact and/or technical reasoning to reasonably support the determination that annealing at a lower temperature at a time less than 4 hours necessarily produces the claimed properties or, alternatively, that the claimed properties would have been obvious otherwise.

While the prior art as a whole suggests that the objectives within the art were the reduction of free radical due to crosslinking, low solubility and no post-irradiation and annealing oxidation, it is not clear from the teachings of the prior art that the skilled artisan would have had a reasonable expectation of achieving the particular recited properties without the hindsight reliance on the annealing times and temperature described in the ’020 patent. Further, while the prior art teaches a number of annealing times and temperatures, the Examiner and the Requester have not shown that, more likely than not, the skilled artisan would have recognized that the particular required properties could be achieved at temperatures below

140°C by optimizing these parameters, namely by increasing the annealing time to at least 4 hours.

Lawton was discussed above. Oonishi does not disclose annealing at all and thus was combined with Dole '83 and Dole '79. RAN 11 and 13. De Boer describes annealing at 140° C for 2 hours and Dole '79 discloses annealing at 140° C and does not disclose an annealing time. De Boer, p. 310, 3rd full ¶; Dole '79, p. 714, 2nd and 3rd full ¶. Although Dole '79 and De Boer describe the elimination of free radicals as observed by ESR and/or a lack of post-annealing oxidation, the Requester and Examiner have presented no persuasive evidence that the skilled artisan would have expected the materials treated in this manner, but at temperatures below 140° C, to display the same elimination of free radicals and lack of post-annealing oxidation reported in Dole '79 and De Boer or the claimed solubility in trichlorobenzene. Finally, Dole '83 reports that annealing after irradiation was known in the art but is silent as to annealing times and temperatures. Dole '83, p. 17, 3rd ¶. However, there is no art of record has been identified which suggests annealing times greater than 4 hours to establish that the claimed properties or the times and temperatures described in the '020 patent are inherent or otherwise obvious to the skilled artisan as discussed above.

The Examiner found that "[a]ll of the documentation applied in the rejections clearly shows a direct correlation between solubility, oxidation and the presence of free radicals, thus it naturally follows that with the solubility met, the claimed oxidation index and level of free radicals are also met." RAN 37. While the evidence suggest some correlation exists between

the reduction of free radicals and reduced oxidation,[21] the evidence does not support finding a clear correlation of one property in the prior art to a reasonable determination that the specific ranges for the properties recited in the claims would have been predictable or obvious to one of ordinary skill in the art. For example, we found persuasive that the skilled artisan would not have been capable of predicting solubility in trichlorobenzene based only on solubility in xylene. Likewise, there is insufficient evidence of record to predict solubility in trichlorobenzene based on a low free radical concentration or evidence of no post-annealing oxidation or vice versa.

SECONDARY CONSIDERATIONS

In reversing the Examiner's position on obviousness for the reasons discussed above, we find it unnecessary to discuss the secondary consideration arguments of Patent Owner in detail.

SUMMARY

We affirm the Examiner's rejection of claims 1-6 under 35 U.S.C. § 102(b) as anticipated by Lue, as evidenced by the Clough Declaration. We decline to reach the remaining rejections of claims 1-6. We reverse each of the rejections of claims 7-12 maintained by the Examiner.

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[21] *See* 1st Clough Decl. ¶ 11 (testifying that Dole made a correlation be the elimination of all free radicals and no post-annealing oxidation, but Dr. Clough does not opine regarding a correlation with solubility in trichlorobenzene); *see also* the various properties tested in the prior art references.

TIME PERIOD FOR RESPONSE

In accordance with 37 C.F.R. § 41.79(a)(1), the "[p]arties to the appeal may file a request for rehearing of the decision within one month of the date of: . . . [t]he original decision of the Board under § 41.77(a)." A request for rehearing must be in compliance with 37 C.F.R. § 41.79(b). Comments in opposition to the request and additional requests for rehearing must be in accordance with 37 C.F.R. § 41.79(c) & (d), respectively. Under 37 C.F.R. § 41.79(e), the times for requesting rehearing under paragraph (a) of this section, for requesting further rehearing under paragraph (d) of this section, and for submitting comments under paragraph (c) of this section may not be extended.

An appeal to the United States Court of Appeals for the Federal Circuit under 35 U.S.C. §§ 141-144 and 315 and 37 C.F.R. § 1.983 for an *inter partes* reexamination proceeding "commenced" on or after November 2, 2002 may not be taken "until all parties' rights to request rehearing have been exhausted, at which time the decision of the Board is final and appealable by any party to the appeal to the Board." 37 C.F.R. § 41.81. *See also* MPEP § 2682 (8th ed., Rev. 7, July 2008).

In the event neither party files a request for rehearing within the time provided in 37 C.F.R. § 41.79, and this decision becomes final and appealable under 37 C.F.R. § 41.81, a party seeking judicial review must timely serve notice on the Director of the United States Patent and Trademark Office. See 37 C.F.R. §§ 90.1 and 1.983.

AFFIRMED-IN-PART

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PATENT OWNER:

LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK
600 SOUTH AVENUE WEST
WESTFIELD, NJ 07090

THIRD-PARTY REQUESTER:

JEFF B. VOCKRODT, ESQ.
HUNTON & WILLIAMS LLP
1900 K. STREET NW, SUITE 1200
WASHINGTON, DC 20006-1109

BRYAN RUTSCH, ESQ.
KIRKLAND & ELLIS LLP
300 NORTH LaSALLE
CHICAGO, IL 60654

US006818020B2

(12) **United States Patent**
Sun et al.

(10) **Patent No.: US 6,818,020 B2**
(45) **Date of Patent: Nov. 16, 2004**

(54) **NON-OXIDIZING POLYMERIC MEDICAL IMPLANT**

(75) Inventors: **Deh-Chuan Sun**, Allendale, NJ (US); **Casper F. Stark**, Allendale, NJ (US)

(73) Assignee: **Howmedica Osteonics Corp.**, Mahwah, NJ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **10/461,636**

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(60) Continuation of application No. 10/041,118, filed on Jan. 8, 2002, now Pat. No. 6,664,308, which is a continuation of application No. 09/604,868, filed on Jun. 28, 2000, now Pat. No. 6,372,814, which is a continuation of application No. 09/012,345, filed on Jan. 23, 1998, now Pat. No. 6,174,934, which is a continuation of application No. 08/733,067, filed on Oct. 16, 1996, now Pat. No. 5,728,748, which is a continuation of application No. 08/439,028, filed on May 11, 1995, now Pat. No. 5,650,485, which is a division of application No. 08/320,705, filed on Oct. 7, 1994, now Pat. No. 5,449,745, which is a division of application No. 08/070,074, filed on Jun. 1, 1993, now Pat. No. 5,414,049.

(51) **Int. Cl.**[7] **A61F 2/30**; A61F 2/02; C08F 6/00

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Primary Examiner—Susan Berman
(74) *Attorney, Agent, or Firm*—Lerner, David, Littenberg, Krumholz & Mentlik, LLP

(57) **ABSTRACT**

A medical implant made of polymeric material having an increased oxidation resistance is formed by a method including the steps of placing a resin powder in a sealed container. A substantial portion of the oxygen is removed from the sealed contained by either a vacuum, an oxygen absorbent or by flushing with inert gas. The container is then repressurized with a gas such as nitrogen, argon, helium or neon so that long term storage may be possible. On use, the resin in transferred to a forming device which both melts and forms the resin in an oxygen reduced atmosphere to produce a polymeric raw material such as a rod or bar stock. The medical implant is then formed from this raw material annealed and sealed in an airtight package in an oxygen reduced atmosphere. The implant is then radiation sterilized and thereafter annealed in the package for a predetermined time and temperature sufficient to form cross-links between any free radicals in neighboring polymeric chains.

12 Claims, No Drawings

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NON-OXIDIZING POLYMERIC MEDICAL IMPLANT

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. Ser. No. 10/041,118 filed Jan. 8, 2002, U.S. Pat. No. 6,664,308 which is a continuation of U.S. Ser. No. 09/604,868 filed Jun. 28, 2000, U.S. Pat. No. 6,372,814 which is a continuation of U.S. Ser. No. 09/012,345 filed Jan. 23, 1998, U.S. Pat. No. 6,174,934, which is a continuation of U.S. Ser. No. 08/733,067 filed Oct. 16, 1996, U.S. Pat. No. 5,728,748, which is a continuation of U.S. Ser. No. 08/439,028 filed May 11, 1995, U.S. Pat. No. 5,650,485, which is a division of U.S. Ser. No. 08/320,705 filed Oct. 7, 1994, U.S. Pat. No. 5,449,745 which is a division of U.S. Ser. No. 08/070,074 filed Jun. 1, 1993, U.S. Pat. No. 5,414,049.

BACKGROUND OF THE INVENTION

This invention relates to medical implants formed of a polymeric material such as ultra-high molecular weight polyethylene, with superior oxidation resistance upon irradiation and a method for making the same.

Various polymer systems have been used for the preparation of artificial prostheses for biomedical use, particularly orthopedic applications. Among them, ultra-high molecular weight polyethylene is widely used for articulation surfaces in artificial knee and hip replacements. Ultra-high molecular weight polyethylene (UHMWPE) has been defined as those linear polyethylenes which have a relative viscosity of 2.3 or greater at a solution concentration of 0.05% at 135° C. in decahydronaphthalene. The nominal weight—average molecular weight is at least 400,000 and up to 10,000,000 and usually from three to six million. The manufacturing process begins with the polymer being supplied as fine powder which is consolidated into various forms, such as rods and slabs, using ram extrusion or compression molding. Afterwards, the consolidated rods or slabs are machined into the final shape of the orthopedic implant components. Alternatively, the component can be produced by compression molding of the UHMWPE resin powder.

All components must then go through a sterilization procedure prior to use, but usually after being packaged. There exists several sterilization methods which can be utilized for medical applications, such as the use of ethylene oxide, heat, or radiation. However, applying heat to a packaged polymeric medical product can destroy either the integrity of the packaging material (particularly the seal, which prevents bacteria from going into the package after the sterilization step) or the product itself.

Because ethylene oxide may adversely impact environmental and employee safety, gamma ray, x-ray or electron beam radiation has been utilized as a preferred means of sterilization. These types of radiation use a high energy beam to kill bacteria, viruses, or other microbial species contained in the packaged medical products, achieving the goal of product sterility.

However, it has been recognized that regardless of the radiation type, the high energy beam causes generation of free radicals in polymers during radiation. It has also been recognized that the amount of free radicals generated is dependent upon the radiation dose received by the polymers and that the distribution of free radicals in the polymeric implant depends upon the geometry of the component, the type of polymer, the dose rate, and the type of radiation beam. The generation of free radicals can be described by the following reaction (which uses polyolefin and gamma ray irradiation for illustration):

$$\text{Polyolefin} \xrightarrow{\text{gamma rays}} \text{r. where r. are primary free radicals*} \quad (1)$$

*(through C—C chain scission or C—H scission)

Depending whether or not oxygen is present, primary free radicals r~ will react with oxygen and the polymer according to the following reactions as described in "Radiation Effects on Polymers", edited by Roger L. Clough and Shalaby W. Shalaby, published by American Chemical Society, Washington, D.C., 1991.

In the Presence of Oxygen

$$\text{r.} \xrightarrow{O_2} rO_2 \quad (2)$$

$$rO_2 + \text{polyolefin} \text{ ------- } rOOH + P. \quad (3)$$

$$P. + O_0 \text{ ------- } P0_2. \quad (4)$$

$$P0_2. + \text{polyolefin} \text{ ------- } POOH + P. \xrightarrow{O_2} P0_2. \quad (5)$$

$$rO_2., P0_2. \text{ ------- Some chain scission products} \quad (6)$$

$$rOOH, POOH \xrightarrow{\text{room temperature}} \text{free radicals, } rOH, POH \quad (7)$$

$$P. + P0_2 \text{ ------- } POOP \text{ (ester cross-links)} \quad (8)$$

$$2\,P. \text{ ------- } P—P \text{ (C—C cross-links)} \quad (9)$$

In radiation in air, primary free radicals r. will react with oxygen to form peroxyl free radicals $r0_2$., which then react with polyolefin (such as UHMWPE) to start the oxidative chain scission reactions (reactions 2 through 6). Through these reactions, material properties of the plastic, such as molecular weight, tensile, and wear properties, are degraded.

Recently, it was found that the hydroperoxides (rOOH and POOH) formed in reactions 3 and 5 will slowly break down as shown in reaction 7 to initiate post-radiation degradation. Reactions 8 and 9 represent termination steps of free radicals to form ester or carbon-carbon cross-links. Depending on the type of polymer, the extent of reaction 8 and 9 in relation to reactions 2 through 7 may vary. For irradiated UHMWPE, a value of 0.3 for the ratio of chain scission to cross-linking has been obtained, indicating that even though cross-linking is a dominant mechanism, a significant amount of chain scission occurs in irradiated polyethylene.

By applying radiation in an inert atmosphere, since there is no oxidant present, the primary free radicals r. or secondary free radicals P. can only react with other neighboring free radicals to form carbon-carbon cross-links, according to reactions 10 through 12 below. If all the free radicals react through reactions 10 through 12, there will be no chain scission and there will be no molecular weight degradation. Furthermore, the extent of cross-linking is increased over the original polymer prior to irradiation. On the other hand, if not all the free radicals formed are combined through reactions 10, 11 and 12, then some free radicals will remain in the plastic component.

In an Inert Atmosphere

$$r. + \text{polyolefin} \text{ ------- } P. \quad (10)$$

$$2\,r. \text{ ------- } r—r \text{ (C—C cross-linking)} \quad (11)$$

-continued

$$2\,P. \text{-------}\ P{-}P\ (C{-}C \text{ cross-linking}) \tag{12}$$

It is recognized that the fewer the free radicals, the better the polymer retains its physical properties over time. The greater the number of free radicals, the greater the degree of molecular weight and polymer property degradation will occur. Applicant has discovered that the extent of completion of free radical cross-linking reactions is dependent on the reaction rates and the time period given for reaction to occur.

Several prior art patents attempt to provide methods which enhance UHMWPE physical properties. European Patent Application 0 177 522 81 discloses UHMWPE powders being heated and compressed into a homogeneously melted crystallized morphology with no grain memory of the UHMWPE powder particles and with enhanced modulus and strength. U.S. Pat. No. 5,037,928 discloses a prescribed heating and cooling process for preparing a UHMWPE exhibiting a combination of properties including a creep resistance of less than 1% (under exposure to a temperature of 23° C. and a relative humidity of 50% for 24 hours under a compression of 1000 psi) without sacrificing tensile and flexural properties. U.K. Patent Application GB 2 180 815 A discloses a packaging method where a medical device which is sealed in a sterile bag,. after radiation/sterilization, is hermetically sealed in a wrapping member of oxygen-impermeable material together with a deoxidizing agent for prevention of post-irradiation oxidation.

U.S. Pat. No. 5,153,039 relates to a high density polyethylene article with oxygen barrier properties. U.S. Pat. No. 5,160,464 relates to a vacuum polymer irradiation process.

SUMMARY OF THE INVENTION

The present invention relates to a method for providing a polymeric material, such as UHMWPE, with superior oxidation resistance upon irradiation. For the purpose of illustration, UHMWPE will be used as an example to describe the invention. However, all the theories and processes described hereafter should also apply to other polymeric materials such as polypropylene, high density polyethylene, polyester, nylon, polyurethane and poly (methylmethacrylate) unless otherwise stated.

As stated above, while UHMWPE polymer is very stable and has very good resistance to aggressive media except for strong oxidizing acids. Upon sterilization radiation, free radicals are formed which cause UHMWPE to become activated for chemical reactions and physical changes. Possible chemical reactions include reacting with oxygen, water, body fluids, and other chemical compounds while physical changes include density, crystallinity, color, and other physical properties. In the present invention a new sterilization radiation process greatly reduces the adverse effects caused by a conventional radiation process. Furthermore, this new sterilization process does not employ stabilizers, antioxidants, or any other chemical compounds which may have potential adverse effects in biomedical or orthopedic applications.

In the sterilization process of the present invention, a polymeric orthopedic implant component to be sterilized by radiation does not contain oxidants, such as oxygen or water (or moisture), or free radicals. This may be accomplished by obtaining a raw material for the implant manufactured under a special process as described herein and forming a part of the invention.

The finished polymeric orthopedic component is then sealed in an oxidant-free atmosphere. This oxidant-free atmosphere is maintained during radiation. The radiated polymeric component is then subjected to a heat treatment to cross-link all the free radicals within themselves. During this treatment, the condition of oxidant-free atmosphere is maintained. The irradiated, heat treated plastic component is now ready to use. Exposure to oxygen or moisture will not cause oxidation. The oxidation resistance to any oxidizing agent is similar to that of the unirradiated virgin polymer.

It is therefore an object of the invention to provide a polymeric orthopedic implant having superior oxidation resistance after irradiation.

It is still another object of the invention to provide a method for manufacturing such an implant from the resin powder thereof through the final sterilization step so that the implant may thereafter be exposed to air without degradation due to oxidation.

These and other objects are achieved by a method for producing a polymeric medical implant including the steps of placing the polymeric resin in a sealed container and removing a substantial portion of the oxygen from the container. After a predetermined time, the container is repressurized with an inert gas such as nitrogen, argon, helium or neon. The resin is thereafter transferred to a forming device which normally melts and forms the resin in an oxygen reduced atmosphere to produce a polymeric raw material. The polymeric raw material, such as UHMWPE is then machined to an implant such as a tibial tray or a liner for an acetabular cup. The finished part is then sealed into a package in an oxygen reduced atmosphere. The package is of an airtight nature to prevent oxygen or moisture from entering after the package is sealed. The then packaged implant is radiation sterilized and then heat treated for the predetermined time and temperature sufficient to form cross-links between free radicals of the neighboring polymeric chains. This prevents further oxidation once the implant is removed from the package.

In general, the implant is heated for at least 48 hours at a temperature of about 37° C. to about 70° C. and preferably for 144 hours at 50° C.

DESCRIPTION OF THE PREFERRED EMBODIMENT

In the preferred method, a raw polymeric material such as UHMWPE is obtained by, for example, ram extrusion, compression molding, or other forming processes. These methods use virgin polymer powder as a starting material. However, virgin polymer resin powder may contain air or moisture, which may exist in the resin micro-structure or simply deposited on the resin surfaces. If air or moisture is not removed from resin powder prior to the forming process, it can be trapped in the plastic matrix after forming and cannot escape. This is true even with the use of vacuum or gas flushing techniques. During the sterilization radiation process, the trapped air or moisture or both will react with free radicals generated in the plastic to cause oxidation. The trapped moisture can also absorb radiation energy and dissociate into oxygen and hydroxyl free radicals which will also react with the plastic to cause oxidation. Therefore, by removing air and moisture prior to the forming process, oxidation during sterilization radiation can be avoided.

The preferred method for eliminating air and moisture is to apply a vacuum of less than 3" of mercury (76 torr) to the polymer resin for a prescribed time to reduce the levels of air and moisture to a minimal or acceptable value. The level for oxygen is preferably 0.5% (volume by volume and no more than 1%). The moisture level is preferably 10% of relative humidity (and no more than 20% relative humidity). Then sufficient amounts of deoxidizing agents, such as oxygen absorbents and moisture desiccants, are placed together with the polymer resin in a sealed container to reduce the levels

of air and moisture to the minimal or acceptable value. An example of an oxygen absorbent is AGELESS® which is an iron oxide compound and commercially available from Cryovac Division, W. R. Grace & Co., Duncan, S. C. An example of moisture desiccant is silica gel which is commercially available. These materials are placed with the resin in the sealed container for approximately 10 hours. Alternately, or in combination, an inert gas, such as nitrogen, argon, helium or neon is used to flush the container, holding the polymer resin powder, until the levels of air and moisture are reduced to the accepted value. Of course, any combination of the above methods can also be used.

In order to ensure a raw material for an orthopedic implant with no oxygen, not only must the UHMWPE resin powder be free of air and moisture, but the entire forming operation of, for example, ram extrusion, compression molding, or other forming process should be carried out in an inert or low oxygen atmosphere as well. During the forming process, due to high temperature and high pressure applied in the process, UHMWPE polymer chains may be broken to generate free radicals and cross-links. While cross-links generated in the forming process have no adverse effects on material properties, the free radicals produced, as described above, can react with air or other oxidants. Therefore, it is important to maintain the inert atmosphere during the forming process to minimize oxidation.

Any free radicals generated should be eliminated as soon as the forming process is completed by annealing. If the formed UHMWPE contains free radicals and is exposed to air or other oxidants after the forming process, oxidation will occur. The polymer should be annealed at an elevated temperature in an inert atmosphere for a prescribed time. This is because the rate of free radical reactions (reactions 10 through 12) increases with increasing temperature, according to the following general expressions:

$$\frac{dr.}{dt} = k_1[r.] \text{ and } \frac{dP.}{dt} = k_2[P.] \tag{13}$$

Compared to room temperature, an elevated temperature not only increases the reaction rate constants, k_1 and k_2, but also helps free radicals r~ and P. to migrate in the plastic matrix to meet other neighboring free radicals for cross-linking reactions. In general, the desired elevated temperature is between the room temperature and the melting point of the polymer. For UHMWPE, this temperature range is between about 25° C. and about 140° C. However, the preferred annealing temperature range is from about 37° C. to about 135° C. The preferred time and temperature is 130° C. for 20 hours with the minimum annealing time being about 4 hours (requiring a temperature at the high end of the range). It is to be noted that the higher the temperature used, the shorter the time period needed to combine free radicals. Additionally, due to the high viscosity of a UHMWPE melt, the formed UHMWPE often contains residual (internal) stress caused by incomplete relaxation during the cooling process, which is the last step of the forming process. The annealing process described herein will also help to eliminate or reduce the residual stress. A residual stress contained in a plastic matrix can cause dimensional instability and is in general undesirable.

In applications such as for orthopedic implants, the formed UHMWPE is further machined into desired shapes. In general, the machining is done at room temperature and no damage to the plastic will occur. However, certain machine tools, when operated at a high speed, may generate local heat and cause thermal breakdown of UHMWPE polymer chains. In this case, the above described annealing process may be employed to eliminate any newly formed free radicals prior to packaging.

After machining, the polymeric component is packaged in an air tight package in an oxidant-free atmosphere. Thus, all air and moisture must be removed from the package prior to the sealing step. Machines to accomplish this are commercially available, such as from Orics Industries Inc., College Point, N.Y., which flush the package with a chosen inert gas, vacuum the container, flush the container for the second time, and then heat seal the container with a lid. In general, less than 0.5% (volume by volume) oxygen concentration can be obtained consistently. An example of a suitable oxidant impermeable (air tight) packaging material is polyethylene terephthalate (PET). Other examples of oxidant impermeable packaging material is poly(ethylene vinyl alcohol) and aluminum foil, whose oxygen and water vapor transmission rates are essentially zero. All these materials are commercially available. Several other suitable commercial packaging materials utilize a layer structure to form a composite material with superior oxygen and moisture barrier properties. An example of this type is a layered composite comprised of polypropylene/poly(ethylene vinyl alcohol)/polypropylene.

In general, the sterilization radiation step for the packaged implant may take a few hours to complete. As described above, it is imperative that during this time period, the transmission of oxidants, such as oxygen and moisture, into the package be kept to a minimal or at an acceptable value to avoid oxidation.

Following sterilization radiation, a heat treatment step should be performed in an inert atmosphere and at an elevated temperature to cause free radicals to form cross-links without oxidation. If proper packaging materials and processes are used and oxidant transmission rates are minimal, then the oxidant-free atmosphere can be maintained in the package and a regular oven with air circulation can be used for heat treatment after sterilization. To absolutely ensure that no oxidants leak into the package, the oven may be operated under a vacuum or purged with an inert gas. In general, if a higher temperature is used, a shorter time period is required to achieve a prescribed level of oxidation resistance and cross-linking. In many cases, the relationship between the reaction temperature and the reaction rate follows the well-known Arrhenius equation:

$$k_1 \text{ or } k_2 = A^* \exp(-\blacktriangle H/T) \tag{14}$$

where k_1 and k_2 are reaction rate constants from reactions 13 and 14

A is a reaction dependent constant

▲H is activation energy of reaction

T is absolute temperature (K)

However, the temperature should not exceed the distortion temperature of either the packaging material or the plastic components. For UHMWPE, the temperature range is between about 25° C. and about 140° C. However, considering the distortion of the packaging material, the preferred temperature is 37° C. to 70° C.

It is very important to ensure that the number of free radicals has been reduced to a minimal or an accepted level by the heat treatment. This is because the presence of an oxidant causes not only the oxidation of pre-existing free radicals, but also the formation of new free radicals via reactions 2 through 7. When the number of free radicals grows, the extent of oxidation and the oxidation rate will increase according to the following equations:

$$\frac{dr.}{dt} = k_3[r.][O_2] \text{ and } \frac{dP.}{dt} = k_4[P.][0_2] \tag{15}$$

Where free radicals r. and P. can grow in number in the presence of oxidants and in turn increase the oxidation rates.

It is also to be noted that the oxidation reaction rate constants k_3 and k_4 increase with increasing temperature, similar to k_1 and k_2. Therefore, to determine if a certain level of residual free radicals is acceptable or not, it is required to evaluate specific material properties after the plastic sample is stored or aged at the application temperature for a time period which is equal to or longer than the time period intended for the application of the plastic component. An alternative to the method to assess the aging effect is to raise the aging temperature of the plastic sample for a shorter time period. This will increase the reaction rate constants k_3 and k_4 significantly and shorten the aging time. It has been found that an acceptable level of residual free radicals is 1.0×10^{17}/g for UHMWPE use for orthopedic implants.

After heat treatment, the irradiated packaged plastic component is now ready to use. The package can be opened and exposed to air or moisture without causing oxidation. The oxidation resistance of the sterilized plastic component to other oxidants is similar to that of the virgin, unirradiated polymer.

Sample Preparation

A surgical grade UHMWPE rod produced by ram extrusion was machined into samples of desirable shapes. Four sets of samples were prepared using these machined samples by the following methods:

Method A: a UHMWPE sample as machined and unirradiated.

Method B: A UHMWPE sample was heat sealed in a glycol-modified polyethylene terephthalate (PETG, made by Eastman Plastics, Inc., Kingsport, Tenn.) blister in air with an aluminum lid of 0.1 mm in thickness. The sealed blister containing the UHMWPE sheet was sterilized by irradiation of gamma-rays in a dose of 2.5 Mrad. The package was then opened and exposed to room air.

Method C: A UHMWPE sample was placed in a PETG blister and heat sealed in dry nitrogen with an aluminum lid of 0.1 mm in thickness by the Orics Vacuum Gas Flush Heat Seal Machine (Model SLS-VGF-100M for modified atmosphere packaging, made by Orics Industries Inc., College Point, N.Y.) which went through the following cycles:

i) nitrogen gas (moisture-free) flush for five seconds

ii) vacuum to a pressure of equal to or below 3 inches of mercury

iii) nitrogen gas flush (moisture-free) for five seconds

iv) heat seal

The oxygen concentration in the sealed blister was measured by a Mocon Oxygen Analyzer to be 0.325% (volume by volume). The sealed blister containing the UHMWPE sample was sterilized by irradiation of gamma-rays in a dose of 2.5 Mrad. The oxygen concentration in the sealed blister after sterilization radiation was measured to be 0.350%. The package was then opened and exposed to room air.

Method D: Same as Method C, except that after gamma-ray irradiation, the sealed blister containing the UHMWPE sample was heat treated at 50° C. for 144 hours in an oven, then transferred from the oven to room temperature for cooling. After the package was cooled to room temperature, the oxygen concentration was measured by a Mocon Oxygen Analyzer to be 0.360%. The package was then opened and exposed to room air.

Samples prepared by the above methods were used in the following examples for evaluation.

EXAMPLE 1

Two sets of 1-mm-thick UHMWPE sheets prepared by Methods A through D above were oven aged in air at 80° C. for 11 and 23 days respectively. After these sheets were cooled in room temperature, a thin film specimen of about 100 microns in thickness was cut from each of the 1-mm-thick aged UHMWPE sheets and placed in an IR window for a standard FTIR (A Nicolet 710 FTIR system was used) transmission run. A total of 32 spectra (scans) was collected and averaged. To determine the extent of oxidation, the IR absorption peaks in the frequency range of between 1660 and 1800 cm^{-1}, corresponding to carbonyl (C—O) functional groups, were integrated for the peak area. The peak area is proportional to the amount of oxidized UHMWPE in the specimen. To correct for difference in specimen thickness, the integrated peak area was then normalized to the specimen thickness, by dividing by the area of the 1463 cm^{-1} (methyl) peak which is proportional to the specimen thickness. The obtained ratio was defined as oxidation index. A third set of 1-mm-thick UHMWPE sheets prepared by methods A through D, but without oven aging, was also evaluated by the same FTIR method for comparison. Oxidation indices obtained are shown in Table 1:

TABLE 1

Sample	Oxidation Index
Method A/not oven aged	ca. 0.
Method A/11 day oven aging	ca. 0.
Method A/23 day oven aging	ca. 0.
Method B/not oven aged	0.02
Method B/11 day oven aging	0.06
Method B/23 day oven aging	0.11
Method C/not oven aged	0.01
Method C/11 day oven aging	0.04
Method C/23 day oven aging	0.08
Method D/not oven aged	0.01
Method D/11 day oven aging	0.01
Method D/23 day oven aging	0.01

From Table 1 results, it can be seen that the unirradiated UHMWPE sample (Method A) was free of oxidation (below the ETIR detectable level), even after 23 days of oven aging in air at 80° C. On the other hand, the UHMWPE sample irradiated in air (Method B) showed considerable oxidation and the extent of oxidation (as indicated by the oxidation index) increased with increasing aging time. After 23 days of oven aging, the oxidation index reached 0.11. For the UHMWPE sample irradiated in nitrogen (Method C), the initial oxidation index before oven aging was 0.01 which was not significant. However, during the oven aging, the oxidation index increased to 0.04 for 11 days and 0.08 for 23 days respectively. The results indicate that while irradiation in an inert atmosphere is an improvement over oxidation in air, the irradiated plastic component will oxidize further over time once it is exposed to air or other oxidants. In contrast, the UHMWPE sample irradiated in nitrogen followed by heat treatment at 50° C. for 144 hours (Method D), showed an initial oxidation index of only 0.01 which did not increase after 11 or 23 days of oven aging, indicating that this sample has superior oxidation resistance than the samples prepared by Method B or C.

EXAMPLE 2

Two sets of 1-mm-thick UHMWPE sheets prepared by Methods B through D cited in the Sample Preparation were oven aged in air at 80° C. for 11 and 23 days respectively. After these sheets were cooled in room temperature, six tensile specimens with a dumbbell shape according to ASTM D638 (Type IV) were cut from each of the 1-mm-thick aged UHMWPE sheets. A standard tensile test was performed for each specimen at a speed of 2 inches/mm. Another set of 1-mm-thick UHMWPE sheets prepared by Methods B through D cited in the Sample Preparation, but without oven aging, were also evaluated by the same tensile

test method for comparison. Tensile breaking strength results (average of six tests for each condition) are shown in Table 2:

TABLE 2

Sample	Tensile Breaking Strength, psi
Method B/not oven aged	6510
Method B/11 day oven aging	5227
Method B/23 day oven aging	3192
Method C/not oven aged	6875
Method C/11 day oven aging	6400
Method C/23 day oven aging	6004
Method D/not oven aged	6941
Method D/11 day oven aging	7113
Method D/23 day oven aging	6904

From Table 2, tensile breaking strength shows the most deterioration for the sample irradiated in air (Method B). The sample irradiated in nitrogen (Method C) shows some improvement over the sample prepared by Method B. However, the decrease in tensile breaking strength upon oven aging still occurs. In contrast, the sample irradiated in nitrogen followed by heat treatment (50° C. for 144 hours, Method D), shows no change in tensile breaking strength, indicating a superior oxidation resistance.

EXAMPLE 3

Two sets of 1-mm-thick UHMWPE sheets prepared by Methods B and Method D cited in the Sample Preparation were oven aged in air at 80° C. for 11 and 23 days respectively. After these sheets were cooled in room temperature, samples cut from sheets were characterized by a high temperature gel permeation chromatograph (GPC) column for molecular weight distribution. The samples were dissolved in hot trichlorobenzene (TCB). They were then run in the aforementioned solvent at 1.2 ml/mm. using a Jordi Gel Mixed Bed Column, 50 cm×10.0 mm ID., at a column oven temperature of 145° C. on the Waters 15° C. Chromatograph. The injection size was 250 uL of a 0.1% solution. An antioxidant (N-phenyl-2-naphthylamine) was added to all high temperature GPC samples to prevent polymer deterioration.

Prior to sample runs, the column was calibrated using narrow MW polystyrene standards. Since the samples were only partially soluble in the solvent due to cross-linking, the so-determined molecular weight distribution was for the soluble portion only. To determine the extent of cross-linking (solubility), a two hundred milligram sample cut from sheets were dissolved in 100 cc of 1,2,4-trichlorobenzene. Each sample was then heated to approximately 170° C. with N-phenyl-2-naphthyla-mine antioxidant added for 6 hours. The samples were then hot filtered at approximately 170° C. using separate preweighed high temperature filters for each sample.

After filtration, the filters were cooled to room temperature and washed individually with dichloromethane. They were then placed in a convection oven at 105° C. for 6 hours to dry and then reweighed. The weight fraction of the undissolved (cross-linked) portion was then determined based upon the initial weight of 200 mg. To determine the low molecular weight fraction present in each sample, the weight fraction of molecular weight below 10^5 in the soluble portion, determined by GPC, was multiplied by the percent solubility to give weight percent of low molecular weight fraction in each sample. Results are shown in Table 3:

TABLE 3

Sample	Weight Percent Of Soluble Portion Below 10^5	Percent Solubility In Solvent	Weight Percent Of Entire Sample Below 10^5
Method B/without oven aging	28.0	98.2	27.5
Method B/11 day oven aging	36.2	100.0	36.2
Method B/23 day oven aging	48.1	100.0	48.1
Method D/without oven aging	22.7	80.9	18.4
Method D/11 day oven aging	20.5	73.6	15.1
Method D/23 day oven aging	24.2	74.7	18.1

From Table 3, it can be seen that the sample made by Method D contains more cross-linking (i.e., less soluble) than one made by Method B. Upon oven aging, the low molecular weight fraction (defined as below 10^5) in the sample made by Method B increases from 0.275 to 0.48 1 while that of the sample made by Method D remains virtually unchanged at about 0.18 after 23 days of oven aging. The increase in low molecular weight fraction was due to chain scission caused by oxidative reactions. The results indicate that the process of method D can produce an irradiated polymer with a superior oxidation resistance.

EXAMPLE 4

UHMWPE samples of 0.5 inch cubes prepared by Methods B and Method D cited in the Sample Preparation were evaluated for deformation under load (creep resistance). Testing procedures according to ASTM D 621 (A) (24 hr/23° C./1000 psi/90 mm recovery) were used. Results are summarized in Table 4:

TABLE 4

Sample	Deformation Under Load %
Method B	0.80
Method D	0.60

From Table 4, it is concluded that the sample prepared by Method D, the invention, possesses a superior creep resistance (0.6%) to one prepared by Method B(0.8%).

EXAMPLE 5

Two 1-mm-thick UHMWPE samples were annealed in an oven filled with air and dry nitrogen (oxygen concentration is below 0.2%) respectively at 130° C. for 20 hours in order to remove residual stress on the samples. After the sheets were cooled to room temperature in the oven, they were removed from the oven and cut into dumbbell shaped tensile specimens (ASTM D 638, Type V) for evaluation. A standard tensile test according to ASTM D 638 was performed at a speed of 2 inches/min for each of six specimens

annealed in air and in dry nitrogen respectively. Results are shown in Table 5:

TABLE 5

Sample	EAB, %	TYS, psi	TBS, psi	Toughness, lbs-in/in^3
Air annealed	414	3547	6257	10,210
Nitrogen annealed	485	3517	8917	18,960

Note:
EAB - elongation at break
TYS - tensile yield strength
TBS - Tensile breaking strength

From the above table, it is seen that the sample annealed in nitrogen exhibits a higher elongation at break, a higher tensile breaking strength, and a higher toughness, compared to one annealed in air, while the tensile yield strength is similar between the two samples. The results indicate that the sample annealed in nitrogen is more ductile than the one annealed in air. The loss of ductility in the sample annealed in air is due to oxidative chain scission.

To determine oxidation indices in these two samples, a thin film specimen of ca. 100 microns in thickness was cut from each of the 1-mm-thick annealed UHMWPE sheets and placed in an IR window for a standard FTIR (a Nicolet 710 FTIR 10 system was used) transmission run, using the procedures and calculations employed in the Sample Preparation. Oxidation indices obtained are shown in Table 6.

TABLE 6

Sample	Oxidation Index
Air Annealed	0.10
Nitrogen Annealed	ca. 0.0

From the above results, it is seen that the UHMWPE sample annealed in air after ram extrusion showed significant oxidation due to free radicals generated in the forming process. In contrast, the UHMWPE sample annealed in nitrogen showed no oxidation (below the FTIR detectable level). It is concluded that annealing in nitrogen can prevent the polymer from oxidation and produce a polymer with superior ductility.

While several examples of the present invention have been described, it is obvious that many changes and modifications may be made thereunto, without departing from the spirit and scope of the invention.

Although the invention herein has been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the principles and applications of the present invention. It is therefore to be understood that numerous modifications may be made to the illustrative embodiments and that other arrangements may be devised without departing from the spirit and scope of the present invention as defined by the appended claims.

What is claimed is:

1. A medical implant comprising an irradiated ultra-high molecular weight polyethylene having a weight average molecular weight greater than 400,000 and a solubility of less than 80.9% in trichlorobenzene.

2. The medical implant as set forth in claim **1** wherein the level of free radicals in the polyethylene is 1.0×10^{17}/gram or less.

3. The medical implant as set forth in claim **1** wherein the polyethylene has a FTIR (Fourier Transform Infra-red Spectroscopy) oxidation index which does not increase with oven aging in air at 80° C. for up to 11 days.

4. The medical implant as set forth in claim **1** wherein the polyethylene has an FTIR (Fourier Transform Infra-red Spectroscopy) oxidation index which does not increase with oven aging in air at 80° C. for up to 23 days.

5. The medical implant as set forth in claim **1** wherein the solvent is 1,2,4-trichlorobenzene.

6. A medical implant comprising an irradiated ultra-high molecular weight polyethylene having a weight average molecular weight greater than 400,000 wherein the level of free radicals is 1.0×10^{17}/gram or less and an oxidation index which does not increase during oven aging in air at 80° C. for 11 days.

7. A medical implant comprising an ultra-high molecular weight polyethylene having a weight average molecular weight greater than 400,000 irradiated and annealed at temperature greater than 25° C. for a sufficient time to have a solubility of less than 80.9% in trichlorobenzene and a non-increasing FTIR oxidation index during oven aging in air at 80° C. for up to 11 days.

8. The medical implant as set forth in claim **7** wherein the FTIR oxidation index does not increase with oven aging in air at 80° C. for up to 23 days.

9. The medical implant as set forth in claim **7** wherein the weight percent of the polyethylene having a molecular weight below 100,000 is less than 18.4%.

10. A medical implant comprising an ultra-high molecular weight polyethylene having a weight average molecular weight greater than 400,000 irradiated and annealed at a temperature greater than 25° C. for a sufficient time to have a level of free radicals of 1.0×10^{17}/gram or less and an oxidation index which does not increase during oven aging in air at 80° C. for 11 days.

11. A medical implant comprising an ultra-high molecular weight polyethylene having a weight average molecular weight greater than 400,000 irradiated and annealed at a temperature greater than 25° C. for a sufficient time to have a non-increasing FTIR oxidation index of 0.01 during oven aging in air at 80° C. for 11 days.

12. A medical implant comprising an ultra-high molecular weight polyethylene having a weight average molecular weight greater than 400,000 irradiated and annealed at a temperature greater than 25° C. for a sufficient time to have a non-increasing ETIR oxidation index of 0.01 or less during oven aging in air at 80° C. for 11 days and a solubility of less than 80.9% in trichlorobenzene.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,818,020 B2 Page 1 of 1
DATED : November 16, 2004
INVENTOR(S) : Deh-Chuan Sun and Casper F. Stark

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 12,
Line 52, "ETIR" should read -- FTIR --.

Signed and Sealed this

Nineteenth Day of April, 2005

Jon W. Dudas

JON W. DUDAS
Director of the United States Patent and Trademark Office

United States Court of Appeals
for the Federal Circuit

Howmedica Osteonics Corp. v. Smith & Nephew, Inc., 2015-1498,-1503

CERTIFICATE OF SERVICE

I, Robyn Cocho, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Counsel Press was retained by MCANDREWS, HELD & MALLOY, LTD., Attorneys for Appellant to print this document. I am an employee of Counsel Press.

On **September 24, 2015** counsel has authorized me to electronically file the foregoing **Corrected Opening Brief for Appellant** with the Clerk of Court using the CM/ECF System, which will serve via e-mail notice of such filing to all counsel registered as CM/ECF users, including any of the following:

David K. Callahan
Latham & Watkins LLP
330 North Wabash Avenue, Suite 2800
Chicago, IL 60611
312-876-7700
david.callahan@lw.com

Bryan S. Hales
Kirkland & Ellis LLP
300 North LaSalle Street
Chicago, IL 60654
312-862-2000
bhales@kirkland.com

Counsel for Cross-Appellant
Zimmer, Inc.

Bradley T. Lennie
Jeffrey Vockrodt
Hunton & Williams LLP
2200 Pennsylvania Ave., NW
Washington, DC 20037
202-955-1914
blennie@hunton.com
jvockrodt@hunton.com

Counsel for Cross-Appellant
Smith & Nephew, Inc.

Paper copies will also be mailed to the above principal counsel at the time paper copies are sent to the Court.

Upon acceptance by the Court of the e-filed document, six paper copies will be filed with the Court within the time provided in the Court's rules.

September 24, 2015

/s/ Robyn Cocho
Robyn Cocho
Counsel Press

CERTIFICATE OF COMPLIANCE

The undersigned hereby certifies that the foregoing **CORRECTED BRIEF FOR PLAINTIFF-APPELLANT HOWMEDICA OSTEONICS CORP.** complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B). The brief contains 13,956 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii). This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft® Word 2003 in Times New Roman 14-point format.

/s/ Patricia J. McGrath
Patricia J. McGrath
Counsel for Plaintiff-Appellant
Howmedica Osteonics Corp.